UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Lynn Vendinello, attest that I am the Director of the Communications Services and Information Division, Office of Program Support of the United States Environmental Protection Agency (EPA) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

1. April 3, 1985. Glyphosate EPA Reg. # 524-308 Mouse oncogenicity study (from William Dykstra to Robert Taylor) (4 pages).
2. March 4, 1985. Consensus Review of Glyphosate (to Robert Taylor) (4 pages).
3. February 26, 1985. Use of historical data in determining the weight of evidence from kidney tumor incidence in the Glyphosate two-year feeding study; and some remarks on false positives (from Herbert Lacayo to Reto Engler) (5 pages).
4. December 12, 1985. EPA Reg. # 524-308 Roundup; Glyphosate; Pathology Report on Additional Kidney Sections (from William Dykstra to Robert Taylor) (3 pages).
5. February 24, 1986. Transmittal of the Final FIFRA Scientific Advisory Panel Reports on the February 11-12, 1986 Meeting (to Steven Schatzow) (5 pages).
6. June 1986. EPA Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient (EPA OPTS) (181 pages).

Subscribed under the penalty of perjury on this 20th day of September, 2023.

Lynn Vendinello

Lynn Vendinello, Director
Communications Services and Information Division
Office of Program Support

CERTIFICATION OF TRUE COPY

I, Jennifer Clark, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Clark, Jennifer

Digitally signed by Clark, Jennifer
Date: 2023.09.25 20:24:43 -04'00'

Jennifer Clark
Associate General Counsel
General Law Office
Office of General Counsel

Date:_____

Glyphosate/Tox

Caswell file

40

004370

Reviewable Glyphosate

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM APR 3 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Glyphosate; ~~EPA~~ Reg.#: 524-308; mouse oncogenicity study
Caswell #: 661A
Accession #: 251007-014

TO: Robert Taylor
Product Manager (25)
Registration Division

4/1/85

THUR: Robert P. ~~Zendzian~~, Ph.D.
Acting Head, Review Section IV
Toxicology Branch
Hazard Evaluation Division (TS-769)

FROM: William Dykstra, Ph.D.
Toxicology Branch
Hazard Evaluation Division (TS-769)

William Dykstra 3/29/85

Wm Dykstra 4/2/85

Conclusions:

1. Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data.

2. The information on the oncogenicity of glyphosate was evaluated by a Toxicology Branch AD Hoc Committee which concluded that this was an oncogenic response. A copy of the consensus report of the committee is attached.

Review:

1. A chronic feeding study of Glyphosate in mice (Biodynamics # BDN-77-420; Project No. 77-2061; 7/21/83).

Test Material:

Glyphosate technical, purity = 99.7%; fine, white clumped powder; lot number, NB178260813; NB178261017.

Groups of 50 male and 50 female randomized CD-1 mice, individually caged, were administered diets containing 0, 1000, 5000, and 30,000 ppm of test material for 24 months.

Parameters evaluated were toxic signs, mortality, body weight, food consumption, water consumption and hematology at 12, 18 and 24 months.

All animals were necropsied and selected organs were weighed. Tissues were stained in H and E and examined microscopically.

Statistical analyses of the data were performed.

Results:

No treatment-related toxic signs were noted during the study. Mortality was low during the first 18 months of the study as shown in the table below as reported:

Cumulative Mortality

DOSE	Males			Females		
(ppm)	12 Mo	18 Mo	24 Mo	12 Mo	18 Mo	24 Mo
0	9	12	30	3	15	30
1,000	9	19	34	4	16	38
5,000	7	14	33	1	8	23
30,000	4	11	24	5	13	27

Body weight was consistently decreased for males and to a lesser extent, females at the 30,000 ppm dosage level during the study at several sampling intervals. Changes in body weight at the low- and mid-dose group were variable and not dose-related.

Food consumption showed no compound-related or dose-related effect. Hematological values although significant in some instances did not show a consistent dose-related response.

Necropsy did not show treatement-related lesions. There was good correlation between gross and microscopic findings. The relative and absolute weight of the testes and ovaries were increased in high dose males and females, but no histopathological finding was present as a underlying factor.

Renal tubule adenomas occurred in male mice in the following manner as reported:

Dose (ppm)	0	1,000	5,000	30,000
Number examined	49	49	50	50
Renal tubule adenoma	0	0	1	3

They occurred in male mice 4029, 4032 and 4041 of the high-dose, and male 3023 of the mid-dose group and all were unilateral.

These tumors are rare, dose related and considered compound-related. These tumors were present at terminal kill.

Other neoplasmas were considered unrelated to treatment. No effect on latency was noted.

Significant trends and significant high-dose effects were observed in non-neoplastic lesions. The lesions considered treatment-related were hepatocyte hypertrophy, central lobular hepatocyte necrosis and chronic interstitial nephritis in high-dose males and proximal tubule epithelial basophilia and hypertrophy in high-dose females.

The table below shows the incidence of these lesions as reported:

	Control	Low	Mid	High	Linear Trend
Central lobular hepatocyte hypertrophy					
- males	9/49	5/50	3/50	17/50	b
- females	3/49	5/50	5/50	1/49	
Central lobular hepatocyte necrosis					
- males	0/49	2/50	2/50	10/50[a]	b
- females	2/49	1/50	4/49	2/49	
Chronic interstitial nephritis					
- males	5/49	2/49	7/50	12/50	b
- females	4/50	8/50	2/50	4/50	
Proximal tubule epithelial basophilia and hypertrophy					
- males	15/49	10/49	15/50	7/50	
- females	0/50	2/50	4/50	9/50[a]	a

[a]Statistically significant increase compared to control ($p \leq 0.01$) using the Chi-Square test (uncorrected for continuity).

[b]Statistically significant linear trend ($p \leq 0.01$) using the Cochran-Armitage test.

Conclusion:

Glyphosate was oncogenic in male mice producing a dose-related increased in renal tubule adenomas, a rare tumor. Dose-related non-neoplastic lesions occurred in both sexes. The NOEL for systemic effects was 5000 ppm. At the LEL, 30,000 ppm, there were increased hepatocyte hypertrophy, hepatocyte necrosis and interstitial nephritis in male mice and an increased incidence of proximal tubule epithelial basophilia and hypertrophy in female mice. Additionally, there were decreased body weights in male and female mice at 30,000 ppm which are considered compound-related.

Classification:

Core minimum data.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 4 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Consensus Review of Glyphosate
Caswell No. 661A

TO: Robert Taylor
Product Manager
Herbicide - Fungicide Branch
Registration Division

On February 11, 1985, a group of Toxicology Branch personnel met to evaluate and discuss the data base on Glyphosate, and in particular the potential oncogenic response of Glyphosate.

A. The following persons were in attendance:

Theodore M. Farber, Ph.D.
Chief, Toxicology Branch

Louis Kasza, D.V.M., Ph.D.
Pathologist

Bertram Litt, Statistician

Herbert Lacayo, Ph.D.
Statistician

Reto Engler, Ph.D.

William Dykstra, Ph.D.
Reviewer

Steve Saunders, Ph.D.

Laurence Chitlik, D.A.B.T.

The signatures above indicate concurrence with this concensus report.

B. The material available for review consisted of a package issued on January 25, 1985 (attached) and a letter from Monsanto (dated February 5, 1985), rebutting the significance of renal mouse tumors.

C. Evaluation of the Facts:

1. Long-term/Pivotal Studies:

a) A 26-month rat study showed a NOEL at 30 mg/kg/day which was the HDT. The oncogenic potential at this level was negative, corroborated by an outside consultant. Although some thyroid tumors were observed in female rats in this study they were generally discounted in their significance, in and of themselves. However, it should be noted that on a mg/kg/day basis the exposure of rats was less than 1/100 of the exposure of mice (4,500 mg/kg/day). Since a toxic, or MTD, level was not reached in this study, the panel raised the conjectural issue that at toxic levels at or close to a MTD, tumors might have been induced.

b) The NOEL in a rat 3-generation reproduction study was 10 mg/kg/day. In separate teratogenicity studies feto toxic effects were noted in rats and rabbits at levels which caused significant maternal toxicity, including death; terata were not observed (ibid). These results were, however, not entered into the discussion on Glyphosate.

2. Mutagenicity Assays:

Glyphosate was tested for mutagenic activity (1) Reverse Mutation in S. typhimurium. and E. coli with and without microsomal activation, (2) Ames Assay with and without activation, (3) CHO cells with and without activation, (4) DNA repair in rat hepatocytes, (5) Rec-assay in B subtilis, and (6) Dominant lethal assay in mice. All these tests were negative, tests 1-3 are fairly well predictive of oncogenic response while 4-6 are less appropriate. An in vivo bone marrow cytogenetics study was also performed. It was negative, but scientifically not acceptable. In summary, several appropriate and scientifically acceptable tests are supportive of non-oncogenic potential of Glyphosate.

3. In the chronic mouse study carried out by Biodynamics (#BDN-77-420) renal tubule adenomas were observed in males.

Dose (ppm)	0	1000	5000	30,000
No. Exposed	49	49	50	50
Tumors	0	0	1	3

See review of W. Dykstra (dated 9/4/84).

This is a rare tumor even in Charles River CD-1 male mice. Biodynamics historical data (included in package) show that this tumor was observed only 3 times in 14 male control groups ranging in size between 51 and 60 mice.

The probability of observing this tumor 4 times or more in 198 mice (the total number of mice examined in the Glyphosate study) is p = 0.0064 when considering the historical control of the same laboratory. Even considering other reported historical controls, the p-value is low, about 0.01 indicating that it is very unlikely that the glyphosate test group is consistent with any historical controls. (See review by Dr. Lacayo).

In addition, the response rate (see above) seems to be related to the dose.

Therefore, it was the concensus of the group that the renal tubular adenomas were related to compound administration, since their frequency was not consistent with the historical controls and there is a trend indicating dose dependency.

3a. The group noted that there were other non-oncogenic, i.e., toxicological changes apparant in the kidney and liver e.g., central lobular hepatocyte hypertrophy and necrosis and chronic interstitial nephritis in males and proximal tubule epithelial basophylia and hypertrophy in females. The group discussed the possibility of kidney irritation and formulation of crystals but noted that kidney or bladder precipitaters were not reported for this assay. Therefore, a conclusion mitigating the renal tumors could not be reached.. (See page 10 of contractor review).

D. Other Considerations:

The review panel recognizes that the exposure of mice was at a very high level 4.5 g/kg/day. Precipitation of Glyphosate in the kidneys might have occurred but none was reported. The panel believes that additional sectioning of new blocks of male kidneys might help in the interpretation of the study results. The kidney tumors as reported, were unilateral (pers. communication by Dr. Dykstra, after the panel meeting); additional histopathology could resolve the issue of whether this is a valid observation or due to not "finding" the tumors in the particular block analyzed.

The panel also believes that realistic exposure assessment, both for dietary and worker exposure are of singular importance. For example, the limit of detecting residue tolerances may overestimate exposure. Particular emphasis also should be given to residues in water, since Glyphosate has been used for aquatic weed control (EUP) and this use may become the subject of a permanent registration.

E. Classification of Glyphosate:

In accordance with EPA proposed guidelines (FR of Nov. 23, 1984) the panel has classified Glyphosate as a Category C oncogen.

ADDENDUM:

The letter by Monsanto (Feb. 4, 1985) has been considered in these deliberations. Several of the issues raised are, in fact, addressed in the above deliberations, although not point by point. A point by point rebuttal, including those points with little merit, will be done in addition to this evaluation.

Attachments

cc: B. Coberly
Caswell No. 661A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 26 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Use of historical data in determining the weight of evidence from kidney tumor incidence in the Glyphosate two-year feeding study; and some remarks on false positives

TO: Reto Engler, Chief
Scientific Mission Support Staff
TOX/HED/OPP (TS-769C)

FROM: Herbert Lacayo, Statistician
Scientific Mission Support Staff
TOX/HED/OPP (TS-769C)

Herbert Lacayo Feb 26, 1985

THRU: Bertram Litt, Statistics Team Leader
Scientific Mission Support Staff
TOX/HED/OPP (TS-769C)

3/4/85

BACKGROUND

The Glyphosate feeding study (EPA Reg. #: 524-308, Caswell #: 661A, Accession #: 251007-014) on Charles River CD-1 mice generated renal tubular adenomas in male mice at the 5000 and 30000 ppm dose levels. The registrant (Monsanto) claims that such tumors are "unrelated to treatment." (ref.1). In support of that they provide historical data from Bio/dynamics and two other laboratories (ref.2).

With respect to historical data we note the large number and variety of factors which influence the life history of rodents in chronic studies. Hence, it is generally agreed that the most relevant historical controls are experiments from the subject laboratory studied within a 3 to 4 year "window" (ref.3).

SUMMARY

The main purpose of this memo is to show one way historical data may be used to evaluate the significance of tumors in the glyphosate feeding study. When these data are so used we can conclude that Glyphosate dosing has a statistically significant effect (at the p = .006 level) in the production of kidney tumors in male mice. The appropriate procedure is outlined in the next section entitled Use of Historical Data. The last Section, Remarks on False Positives, addresses some comments by Monsanto (Ref.1) on this subject. That section outlines some of the weaknesses in Monsanto's position.

USE OF HISTORICAL DATA

The following information was derived from Reference 2.

Data Source*	p (est.of tumor rate)	Sigma (est.of standard deviation)
Bio/dynamics	.00368	.00212
IRD Corp.	.00437	.00109
Combined	.00399	.00094

The value p = .00368, derived from Bio/dynamics data is a reasonable choice to use as a historical control. The data are from the same laboratory that performed the Glyphosate study and are within the appropriate 3-4 year time "window" (ref.3). Further, the standard deviation of the estimate is reasonably small.

We will now examine the Monsanto contention that the kidney tumors are unrelated to treatment. (i.e. Glyphosate has no effect on kidney tumors). First, consider the tumor rate in the Glyphosate Study: 4/198 = .0202 ---

In contrast, Bio/dynamics has the lower historical rate:

3/815 = .00368

The relevant question is: What is the probability that the 198 CD-1 mice in the Glyphosate study will produce by pure chance 4 or more mice with kidney tumors? Another way of stating this is - How likely are we to have a tumor rate of .0202 --- for the Glyphosate study given that the historical rata is .00368?

Questions of this type may be answered from manipulation of the relevant distribution which, in this case is the Binomial:

$$P(r \text{ out of } n \text{ mice have tumors}) = \binom{n}{r} p^r q^{n-r}$$

Where: n = the # of male mice in the study

r = the # of male mice with kidney tumors

p = .00368, the historical probability that an individual male mouse will develop kidney tumors.

q = 1 - p

*This does not include Hazleton Laboratories America, Inc. due to the small sample size of that data set

Using the above distribution and elementary but tedious calculations, we generate the following table:

# of mice with tumor	Probability that r or more mice will have tumors in a study with 198 male mice
r = 0	1.
1	.518177
2	.165711
3	.037443
4	.006481

This last table indicates that based on a historical rate of p= .00368 that the probability of seeing 3 or more mice with kidney tumors is about .037; and the probability of seeing 4 or more such mice (i.e. seeing what in fact happened) is about .0064. We note that even considering data from I.R.D., the p value is about .01.

Under such circumstances a prudent person would reject the Monsanto assumption that Glyphosate dosing has no effect on kidney tumor production. Another way of saying this is that if Glyphosate were truly unrelated to kidney production we would expect to see 4 or more tumors in less than 1 out of 100 experiments of the type sponsored by Monsanto. Thus, Glyphosate is suspect.

REMARKS ON FALSE POSITIVES

In ref. 1 Monsanto notes that "...if 20 types of lesions were evaluated at a probability level of .05, the number expected to be positive would not be one in 20, but rather the probability would be 64 in 100, an unacceptably high value..." Monsanto is referring to the well-known fact that by examining enough data it is likely that one will find an excess of some tumor type by chance alone; thus generating a false positive.

The Monsanto argument required the following assumptions:

1. A mouse may develop 20 distinct and independent (in the statistical sense) types of tumors.
2. The probability of each tumor type in a typical mouse is .05.

It follows from the above that:

$$P(\text{a mouse has at least one tumor}) = 1 - .95^{20} = .6415$$

Hence in 100 mice one would on the average see 64 with tumors. Monsanto proposes to avoid this "problem" of false positives by analyzing the study" ...at the .01 probability level."

We disagree with the Registrants position. First, even if one did analyze the study at the .01 level as they suggest it would still result (using the same mathematics as before) in seeing 18 mice out of 100 with tumors. And hence one still has the problem of false positives from the registrant's viewpoint. But this causes something worse from a regulatory viewpoint. We have decreased the false positive rate (i.e., the probability of saying that a chemical causes tumors when in fact it does not) at the cost of increasing the false negative rate (i.e., the probability of saying that a chemical doesn't cause tumors when in fact it does). The Registrant wishes to avoid false positives while those concerned with the public health wish to avoid false negatives. Hence, for this reason alone Monsanto's argument is unacceptable.

We further disagree as follows:

1. The two assumptions needed to support the Monsanto argument are themselves in need of support (especially the requirement for statistical independence).
2. False positive results are less likely to occur with rare tumors (ref. 5). And the tumors in question are rare.

Viewpoint is a key issue. Our viewpoint is one of protecting the public health when we see suspicious data. it is not our job to protect registrants from false positives. We sympathyze with the Registrants problem; but they will have to demonstrate that this positive result is false.

Finally, we mention that none of the tumors occurred in the control or low dose groups. Instead there was one at 5000 ppm and 3 at the 30000 ppm dose level. This together with the previous comments make it likely that there is a dose-tumor relationship for Glyphosate.

REFERENCES

1. Letter from Monsanto (signed by Frank. S. Serdy) to EPA (Attn: Robert J. Taylor) dated Feb. 5, 1985.

2. Letter from Monsanto (signed by Robert W. Street) to EPA (Attn: Robert J. Taylor) dated March 20, 1984.

3. J.K. Haseman, et al: Use of Historical Control Data in Carcinogenicity Studies in Rodents - Toxicologic Pathology - 12:126-134. 1984.

4. TOX Branch Memo from William Dykstra to Robert Taylor dated 9/4/84.

5. T.R. Fears et al: False-Positive and False-Negative Rates for Carcinogenicity. Cancer Research. 271:1941-1945. July 1977.

File last updated 3/12/85

DRAFT

ACCEPTABLE DAILY INTAKE DATA

RAT,Older NOEL mg/kg	NOEL ppm	S.F.	ADI mg/kg/day	MPI mg/day(60kg)
10.000	200.00	100	0.1000	6.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Grain Crops(64)	0.100	13.79	0.02069
Avocados(6)	0.200	0.03	0.00009
Citrus Fruits(33)	0.200	3.81	0.01144
Coffee(36)	1.000	0.75	0.01119
Grapes, inc raisins(56)	0.100	0.49	0.00074
Leafy Vegetables(80)	0.200	2.76	0.00828
Nuts(101)	0.200	0.10	0.00031
Pome Fruits(126)	0.200	2.79	0.00837
Root Crop Veg(138)	0.100	11.00	0.03299
Seed&Pod Veg(143)	0.200	3.36	0.01098
Palm Oil(202)	0.100	0.03	0.00005
Pistachio nuts(210)	0.200	0.03	0.00009
Asparagus(5)	0.200	0.14	0.00043
Bananas(7)	0.200	1.42	0.00426
Olives(104)	0.100	0.06	0.00009
Stone Fruits(151)	0.200	1.25	0.00374
Sugar,cane&beet(154)	2.000	3.64	0.10915
Molasses(96)	20.000	0.03	0.00920
Cranberries(44)	0.200	0.03	0.00009
Cottonseed (oil)(41)	15.000	0.15	0.03375
Kidney(203)	0.500	0.03	0.00023
Liver(211)	0.500	0.03	0.00023
Peanuts(115)	0.100	0.36	0.00054
Guava(184)	0.200	0.03	0.00009
Papayas(109)	0.200	0.03	0.00009
Mangoes(83)	0.200	0.03	0.00009
Soybeans (oil)(148)	6.000	0.92	0.08263
Pineapple(123)	0.100	0.30	0.00044
Fish,shellfish(59)	0.250	1.08	0.00406
Cucurbits(49)	0.100	2.84	0.00426
Fruiting Vegetables(60)	0.100	2.99	0.00449
Small Fruit,berries(146)	0.100	0.83	0.00124
Hops(73)	0.100	0.03	0.00005
Potable Water(198)	0.500	133.33	1.00000
Tea(162)	4.000	0.07	0.00429

MPI	TMRC	% ADI
6.0000 mg/day(60kg)	1.3686 mg/day(1.5kg)	22.81

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Unpublished,Tox Approved 2F2680,2G2686

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Soybeans (oil)(148)	4.000	0.92	0.05509
Coconut(35)	0.100	0.03	0.00005

[illegible]	TMRC	%cDI
3.0000 mg/day(60kg)	1.4238 mg/day(1.5kg)	23.73

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Current Action [illegible]

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Fish,Shellfish(5%)	0.000	1.00	0.0000

ADI	TMRC	% ADI
3.0000 mg/day(60kg)	1.4238 mg/day(1.5kg)	23.73

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(44)

CASWELL FILE

Glyphosate / Tox

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

004855
Releasable

DEC 12 1985

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. #: 524-308; Roundup; Glyphosate; Pathology Report on Additional Kidney Sections
Caswell No. 661A
Accession No. 259621

TO: Robert Taylor
Product Manager (25)
Registration Division (TS-767)

THRU: Robert P. Zendzian, Ph.D. 12/12/85
Acting Head, Review Section IV
Toxicology Branch
Hazard Evaluation Division (TS-769)

FROM: William Dykstra, Ph.D. William Dykstra 12/12/85
Toxicology Branch
Hazard Evaluation Division (TS-769)

12/12/85

Requested Action:

Review pathology report on additional kidney sections.

Background:

Glyphosate was considered oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The incidence of this tumor was 0, 0, 1, and 3 in the control, low-, mid-, and high-dose groups, respectively.

Additional evaluation of all original renal sections identified a small renal tubular adenoma in one control male (animal No. 1028) which was not diagnosed as such in the original pathology report.

Subsequently, Toxicology Branch recommended that additional renal sections be cut and evaluated from all control and glyphosate treated male mice.

This review contains the evaluation of the submitted results of the additional sectioning and pathological data.

Conclusion:

The results of the additional pathological evaluation on re-cut kidney sections in male mice demonstrated no additional tumors were present. The significance of this finding will be determined later by the Ad Hoc committee.

Review:

1. The pathology report of additional kidney sections submitted by the registrant (Monsanto) showed that the renal tubule adenoma incidence in male mice was as follows:

Dose (ppm)	0	1000	5000	30,000
Animal number			3023	4029,4032,4041
Renal tubule adenoma	0	0	1	3
No. examined	49	49	50	50

The additional tumor in the control group which had been diagnosed from the re-evaluation of the original slides was not present in the re-cut kidney sections.

Toxicology Branch's pathologist (report attached) stated that the control tumor "does not represent a pathophyioloically significant change".

Statistical analysis of the tumor results showed no significant ($P<0.05$) difference in the incidence of renal tubule adenoma between control and treated groups.

However, the test for linear trend in proportions resulted in a $p=0.016$ which is statistically significant.

According to the registrant's pathology report, non-neoplastic kidney lesions did not reveal evidence of an ongoing chemically induced neprotoxicity.

Based on the original report and the new report, Toxicology Branch concludes that chronic interstitial nephritis occurred in compound-related manner in males at the high-dose as is shown below:

	Males (Chronic Interstitial Nephritis)			
Dose (ppm)	0	1000	5000	30,000
Incidence				
Original report	5/49	2/49	7/50	12/50
New report	5/49	1/49	7/50	16/50

Bill Dykstra (46)

Glyphosate/Tox

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Releasable

FEB 24 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Transmittal of the Final FIFRA Scientific Advisory Panel Reports on the February 11-12, 1986 Meeting

TO: Steven Schatzow, Director
Office of Pesticide Programs (TS-766)

The above mentioned meeting of the FIFRA Scientific Advisory Panel (SAP) was an open meeting held in Arlington, Virginia to review the following topics:

(1) A set of scientific issues being considered by the Agency in connection with the Registration Standard for Glyphosate;

(2) A set of scientific issues in connection with the Agency's proposed action on the non-wood uses of Pentachlorophenol as set forth in the Position Document 4;

(3) A set of scientific issues being considered by the Agency in connection with the Registration Standard for Oryzalin;

(4) A set of scientific issues being considered by the Agency in connection with the Registration Standard for Amitraz;

(5) A set of scientific issues being considered by the Agency in connection with the Registration Standard for Acephate;

(6) A set of scientific issues being considered by the Agency in connection with Subdivision U of the Pesticide Assessment Guidelines.

Please find attached the SAP's final reports on the six issues discussed at the meeting.

Stephen L. Johnson, Executive Secretary
FIFRA Scientific Advisory Panel (TS-769)

Attachments

cc: Panel Members
John A. Moore
James Lamb
Al Heier
Susan Sherman
John Melone
Douglas Campt
EPA Participants

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being Considered by the Agency in Connection with the Registration Standard for Glyphosate

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the data base supporting the Environmental Protection Agency's (EPA) decision to reclassify Glyphosate as a class C (possible human) carcinogen. The review was conducted in an open meeting held in Arlington, Virginia, on February 11, 1986. All Panel members, except Dr. Thomas W. Clarkson, were present for the review. In addition, Dr. David Gaylor, Director of the Biometry Staff at the National Center for Toxicological Research, served as an ad hoc member of the Panel.

Public notice of the meeting was published in the Federal Register on Friday, January 17, 1986 (Citation 51-FR2568).

Oral statements were received from staff of the Environmental Protection Agency and from Mr. Robert Harness and Dr. Timothy Long of Monsanto Company.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF SAP RECOMMENDATIONS

General Comments on Carcinogen Classification

The Panel concurs that it is necessary to categorize chemicals as to their apparent carcinogenic risk to man. The Panel is concerned that the categories outlined in the Agency's Cancer Guidelines are somewhat limited in scope. For only a small number of specific chemicals is there epidemiologic evidence of their carcinogenicity in man, either sufficient evidence (Group A) or limited evidence (Group B-1). Thus, most chemicals that are carcinogenic for animals have been placed in Groups B-2 and C. Category D has apparently not been used. The Panel urges the Agency to attempt to develop a more discriminatory classification scheme.

Glyphosate

The Agency requested the Panel to focus its attention upon a set of issues relating to the pesticide Glyphosate. There follows a list of the issues and the SAP's response to each question.

1. Based on the Agency's weight of the evidence assessment with emphasis on the mouse kidney tumors, the Agency has classified Glyphosate as a class C (possible human) carcinogen. The Agency specifically requests any comment that the Panel may wish to present with regard to its assessment of the weight of evidence and subsequent determination of carcinogenicity according to the Agency's Cancer Guidelines.

2. The Agency requests also that the Panel consider what weight should be given to this marginal increase in kidney tumors, the importance of this type of tumor in the assessment of the carcinogenicity of Glyphosate, and the weight placed on historical and concurrent controls for this type of evaluation.

Panel Response:

In the instance of Glyphosate, the Panel concurs that the data on renal tumors in male mice are equivocal. Only small numbers of tumors were found in any group, including those at the highest dose which appear to have exceeded the maximal tolerated dose. The vast majority of the pathologists, who examined the proliferative lesion in the male control animal, agreed that the lesion represented a renal adenoma. Therefore, statistical analysis of the data should utilize this datum. In addition, the statistical analysis shall be age-adjusted; when this is done, no oncogenic effect of Glyphosate is demonstrated using concurrent controls. Nevertheless, the occurrence of three neoplasms in high dose male mice is unusual and using historical controls is statistically highly significant. Furthermore, categorization of the oncogenic risk of Glyphosate is complicated by the fact that doses used in the rat study do not appear to have reached the maximal tolerated dose. Under these circumstances, the Panel does not believe that it is possible to categorize Glyphosate clearly into Group C (possible human carcinogen) or Group E (no evidence of carcinogenicity for humans). The Panel proposes that Glyphosate be categorized as Group D (not classified) and that there be a data call-in for further studies in rats and/or mice to clarify unresolved questions.

Regarding the issue of using historical or concurrent controls, the Panel believes that this has to be decided on a case-by-case basis. For Glyphosate, the historical control data support that there may be reason for concern. However, the level of concern raised by historical control data was not great enough to displace putting primary emphasis on the concurrent controls.

FOR THE CHAIRMAN

Certified as an accurate report of Findings:

Stephen L. Johnson
Executive Secretary
FIFRA Scientific Advisory Panel

Date: 2/24/86

United States
Environmental Protection
Agency

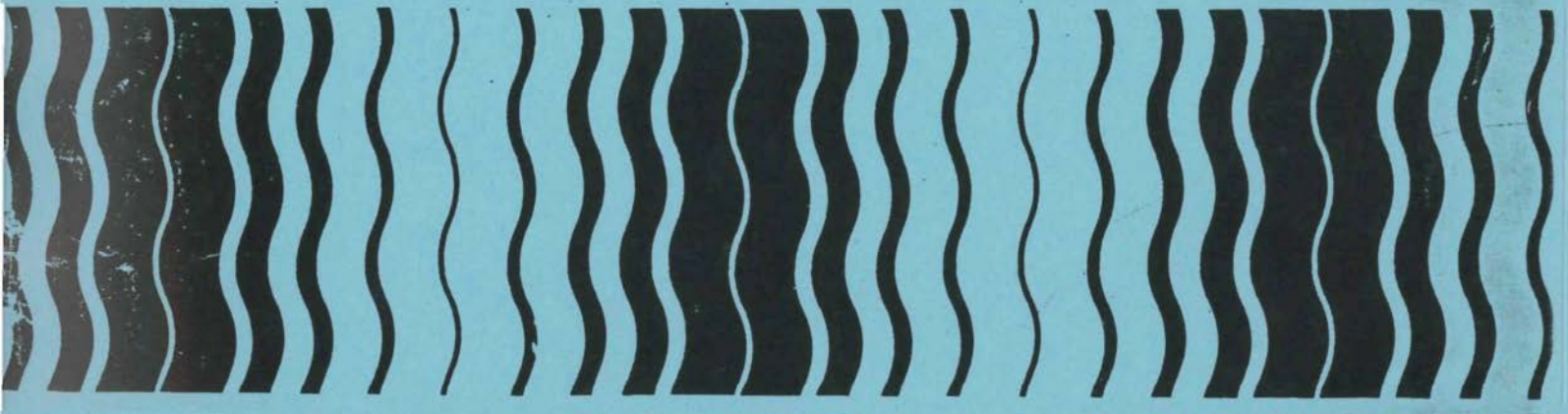
Office of
Pesticides and Toxic Substances
Washington DC 20460

June 1986

Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING GLYPHOSATE AS THE ACTIVE INGREDIENT

CASE NUMBER 0178

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

JUNE 1986

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I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide

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[1]The scientific reviews may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield Virginia 22161 approximately 90 days after issuance.

active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as proposed cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Section V - Requirement for Submission of Generic Data, and Section VI - Requirement for Submission of Product-Specific data. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of Chemicals

The following chemicals are covered by this Registration Standard:

Common name: isopropylamine salt (IPA) of glyphosate
Chemical name: isopropylamine salt of N-(phosphonomethyl) glycine
CAS Number: 38641-94-0
OPP Shaughnessy Number: 103601
Empirical Formula: $C_3H_8NO_5P$
Trade Names: Roundup; Rodeo, Roundup L&G, Shackle, Shackle C
Description of chemical characteristics: White crystalline solid with a melting point of 200 °C with a bulk density of 1.74. This chemical is 1 percent soluble in water at 25 °C; insoluble in ethanol, acetone, or benzene.

Common name: sodium salt of glyphosate
Chemical name: sodium salt of N-(phosphonomethyl) glycine
CAS Number: 38641-94-0
OPP Shaughnessy Number: 103603
Trade Names: Polado
Description of chemical characteristics: White crystalline solid which decomposes at 140 °C with a bulk density of 30 pounds per cubic foot (lb/ft^3). This chemical is soluble in water and insoluble in organic solvents.

B. Use Profile

Type of pesticide: IPA salt herbicide
Sodium salt - plant growth regulator
Pests controlled: Grasses, sedges, and broadleaf weeds (annual and perennial)
Registered Uses: IPA salt (terrestrial food, nonfood crop, and noncrop; aquatic food and noncrop; greenhouse nonfood, domestic outdoor, and forestry); sodium salt (terrestrial food crop).

Predominant Uses:
IPA salt of glyphosate: soybeans, cotton, corn, sorghum, wheat, rice, vegetables, citrus fruits, pome fruits, stone fruits, tropical fruits, pastures, and alfalfa.
Sodium salt of glyphosate: sugarcane.

Mode of activity: Inhibition of amino acid synthesis.

Formulation Types Registered: 1.04 lb active ingredient (ai)/gal emulsifiable concentrate (EC); 0.42, 3, and 4 lb ai/gal soluble concentrate/liquid (SC/L); 5% and 6.6% ai SC/L; 0.5%, 0.96%, and 1% ai liquid ready to use (RTU); and 0.75% and 0.96% ai pressurized liquid (Prl).

Methods of Application: Foliarly, in broadcast application, using conventional ground equipment, handheld, recirculating, and shielded sprayers, wiper applicators and aerial application.

III. AGENCY ASSESSMENT

Summary Science Statement

Glyphosate has low acute toxicity (Category III) for acute oral, acute dermal, and primary eye irritation and is in Category IV for primary skin irritation. It is not teratogenic to rats or rabbits and is not mutagenic. The oncogenic potential is not fully defined at this time. Repeat oncogenic studies are required in mice and rats.

Glyphosate is no more than slightly toxic to birds, aquatic invertebrates, and fish. It does pose a risk to some endangered species.

Glyphosate is stable to hydrolysis and strongly adsorbed onto the soil and has a low potential to contaminate ground water.

Toxicology Characteristics

Acute Toxicity

Acute oral and dermal toxicity data place technical glyphosate in Toxicity Category III. Primary eye and skin irritation data indicate that technical glyphosate is not a primary skin irritant (Toxicity Category IV), and is only minimally irritating to the eye (Toxicity Category III). Acute inhalation or dermal sensitization studies have not been submitted and are required.

Chronic Feeding/Oncogenicity Data

Available chronic feeding/oncogenicity data include chronic feeding/oncogenicity studies in mice and rats and a 1-year chronic feeding study in dogs. A discussion of these studies follows.

The chronic feeding/oncogenicity study in mice tested dosages of 1000, 5000, and 30,000 parts per million (ppm). Glyphosate produced an equivocal oncogenic response in the mouse, causing a slight increase in the incidence of renal tubular adenomas (a benign tumor of the kidney) in males at the highest dose tested of 30,000 ppm. The Toxicology Branch Ad Hoc Oncogenicity Committee tentatively classified glyphosate as a "Class C" oncogen. The studies were reexamined by a consulting pathologist, and data were submitted indicating that an additional kidney tumor had been found in control males (no renal tumors were found in controls in the original examination). The Agency then requested that additional kidney sections from the mouse study be prepared and examined. The resultant microslides were examined by a number of pathologists. These examinations revealed no additional tumors, but confirmed the presence of the tumors identified in the original study report. The apparent lesion in the control kidney was not present in any of the additional sections. After examination of the slides, the Agency concluded that this lesion did not "represent a pathophysiologically significant change."

However the apparent oncogenic response was a marginal response at best. The doses tested were quite high, 3 percent of the diet, and there was no corresponding increase in the incidence of preneoplastic changes, such as hyperplasia or dysplasia, in the target tissue. Further, glyphosate is negative in a number of acceptable mutagenicity studies, therefore the compound is not known to be genotoxic.

Because of the equivocal nature of the findings, the Toxicology Ad Hoc Oncogenicity Committee asked the expert assistance of the FIFRA Science Advisory Panel (SAP) in determining the proper Weight-of-the-Evidence classification of the study. After reviewing all the available evidence, the SAP proposed that glyphosate be classified as "Class D," or having "inadequate animal evidence of oncogenicity." The principal reason for this assessment by the SAP was their determination that, after adjusting for the greater survival in the high dose mice compared to concurrent controls, no statistically significant difference existed. The SAP further noted that, although comparison of these findings to historical control incidences yielded a statistically significant result, this finding did not over-ride the lack of significance of comparisons to concurrent controls. The SAP determined that the oncogenic potential of glyphosate could not be determined from existing data and proposed that the study be repeated in order to clarify these equivocal findings.

After consideration of the expert opinion of the SAP, and reconsideration of all relevant data for this compound in particular the statistical assessment provided by the SAP, the Agency agrees that available data are not sufficient to adequately address the question of whether the apparent effects noted in the mouse study are biologically relevant. Therefore, in order to fully address this question, the Agency is requiring that this study be repeated with a larger number of animals in each test group, so that the statistical power of the study is increased.

Other non-neoplastic changes noted in high-dose male mice included centrilobular hypertrophy and necrosis of hepatocytes, chronic interstitial nephritis, and proximal tubule epithelial cell basophilia and hypertrophy in females. The no-observable effect level (NOEL) for non-neoplastic chronic effects was the mid-dose level, 5000 ppm. This study is acceptable as a chronic feeding study.

The lifetime feeding study in rats tested dietary concentrations of glyphosate of 0, 30, 100, and 300 ppm. These concentrations were adjusted during the course of the study so that actual doses of 0, 3, 10, and 31 mg/kg/day in males and 0, 3, 11, and 34 mg/kg/day in female rats were maintained. Thus, the doses tested in the rat chronic study were about 1/100 of those tested in the mouse study. Although no effect of treatment on the incidence of non-neoplastic lesions was noted, a marginal apparent increase in the incidence of interstitial cell tumors of the testes was observed in the rats. Historical controls were used in the Weight-of-the-Evidence analysis to provide an indication of the range of variability in the background spontaneous incidence of any lesion, and were used to supplement the data provided by a concurrent control group. Because of the absence of a dose-dependent effect, the lack of preneoplastic changes, the wide variability in the spontaneous incidence of this tumor, the similarity in incidences between the high dose group and the historical controls, and lack of any evidence of genotoxicity, it was concluded that the observed incidence did not demonstrate an oncogenic response. An independent review of the data raised a question of possible thyroid carcinoma in high-dose females. After a review of the slides by a consulting pathologist, and a reassessment of all relevant data, including the fact that no effect of treatment on tumor latency or the combined incidences of adenoma and carcinoma was apparent, the Agency concluded that the data did not demonstrate a carcinogenic response in the thyroid.

However, in view of the large differency in doses between the rat and mouse studies, the Toxicology Branch Oncogenicity Review Committee speculated that "a toxic, or MTD [Maximally

Tolerated Dose], was not reached in [the rat] study," and that at doses "close to an MTD, tumors might have been induced." The rat study was rereviewed for evidence that the highest dose tested was an MTD. No effect of treatment on survival, body weight gain, clinical pathology, or findings at necropsy was noted. Therefore, there is no evidence that the highest dose tested was an MTD. A repeat rat study is required in which the highest dose tested is an MTD. This study is acceptable as a chronic feeding study, since an MTD is not required to satisfy Agency guidelines for chronic toxicity studies. Since an MTD was apparently not reached in this study, it does not fulfill the Guideline (§158.135 83-2) requirement for a rat oncogenicity study.

A 1-year chronic feeding study in dogs tested doses of 0, 20, 100, and 500 mg/kg/day, administered by capsule. The only effect of treatment was an apparent decrease in the absolute and relative weights of pituitaries from mid- and high-dose dogs. Additional data have been requested to better assess this apparent effect. The tentative NOEL is 20 mg/kg/day pending submission of requested data.

Subchronic Toxicity Studies

No acceptable rat or dog subchronic feeding studies are available for technical glyphosate. IBT studies submitted for both species were invalid.

A 3-month subchronic study in mice tested dietary concentrations of 0, 5000, 10,000, and 50,000 ppm of technical glyphosate. A decrease in body weight gain was noted in high-dose mice; however, no gross or microscopic changes were observed at necropsy. The study was classified as Supplementary data because hematology, clinical chemistry, and urinalysis measurements were not performed.

The 3-month subchronic study in mice does not have to be repeated because the lifetime chronic feeding study in rats discussed above fulfills the Guideline requirement (§158.135, 82-1) for a subchronic feeding study in a rodent. A 3-month subchronic study in dogs is not required because the 1-year chronic feeding study in dogs discussed above fulfills the Guideline requirement (§158.135 82-1) for a subchronic feeding study in a nonrodent.

A 21-day dermal toxicity study in rabbits testing dermal doses of 100, 1000, and 5000 mg/kg/day for 5 days/week for 3 weeks has been submitted. The only effect noted was slight edema and erythema of the skin at the high dose (5000 mg/kg/day). The no observable effect level (NOEL) for these effects was 1000 mg/kg/day. This study is acceptable. No additional data are required.

Teratology and Reproduction Studies

Acceptable teratology and reproduction studies have been submitted. Therefore, no additional data are required for these topics. A discussion of the acceptable data follows.

A teratology study in rats tested levels of 0, 300, 1000, and 3500 mg/kg/day with no evidence of teratology observed in the study. Evidence of developmental toxicity in the form of unossified sternebrae was noted in fetuses from the high dose (3500 mg/kg/day). This dose was also toxic to dams as evidenced by weight gain deficits, altered physical appearance, and mortality during treatment. The fetotoxic and maternal toxic NOEL for this study is 1000 mg/kg/day.

A teratology study in rabbits tested dosage levels of 0, 75, 175, or 350 mg/kg/day with no evidence of teratogenicity observed. The highest dose tested was toxic to does as evidenced by altered physical appearance and mortality. No treatment-related fetal effects were noted. The NOEL for maternal toxicity is 175 mg/kg/day and the NOEL for fetotoxicity is 350 mg/kg/day.

In the three-generation rat reproduction study and addendum, the most significant finding was focal, unilateral, renal tubular dilation in the kidneys of male pups from the F_{3b} generation of high-dose dams (30 mg/kg/day). The NOEL for this effect was 10 mg/kg/day. No effects on fertility or reproductive parameters were noted.

Mutagenicity

Acceptable studies have been submitted to satisfy the Agency's testing requirements for gene mutations, chromosomal aberrations, and primary DNA damage. Glyphosate was negative for gene mutations in Chinese hamster ovary cells in the presence or absence of microsomal activation. Glyphosate was also negative for gene mutations in bacteria, with or without activation. Glyphosate was negative for chromosomal aberrations in the mouse dominant lethal test and in the *in vivo* cytogenetics assay. No primary DNA effects were seen with glyphosate in the *B. subtilis* rec assay or in the rat hepatocyte DNA repair assay. No additional mutagenicity data are required.

Neurotoxicity

Even though glyphosate is not an organophosate or carbamate pesticide, a delayed neurotoxicity study was conducted in chickens at Industrial Bio-Test Laboratories. Although no

evidence of neurotoxicity was noted in the study, the validation report for this study noted an absence of raw data for dose preparation and administration, body weight measurements, and pathological observations for untreated and positive control birds. After evaluation of the study for scientific content, the study was classified as invalid on the basis of the extensive gaps in the raw data supporting study findings and conclusions.

A repeat neurotoxicity study is not required because the guidelines (§158.135 81-7) require this study only for organophosphate or carbamate pesticides. Glyphosate is neither an organophosphate nor a carbamate pesticide, therefore, the study is not required.

Metabolism

Available metabolism data demonstrate that glyphosate is rapidly excreted by rats, as > 90 percent of the administered dose was eliminated within 48 hours of treatment. In males, the majority of excretion was via the feces (80%), and about 15 percent of the administered dose was eliminated in the urine. In females, about 40 percent of the administered dose was excreted in the urine, which suggests that female rats absorbed more glyphosate from the gastrointestinal tract than did males.

After a single oral or intraperitoneal dose less than 1 percent of the administered dose was retained at 120 hours after treatment. In animals fed 1, 10, or 100 ppm of ^{14}C-glyphosate for 14 days, a steady-state equilibrium between intake and excretion of label was reached within about 8 days. The amount of radioactivity excreted in the urine declined rapidly after withdrawal of treatment. By 10 days after withdrawal, detectable levels of radioactivity were measured in the urine and feces of only the rats fed 10 or 100 ppm of the test diet. Only minimal residues of 0.1 ppm or less remained in the tissues of high-dose rats after 10 days of withdrawal, with no single tissue showing a significant difference in the amount of label retained.

The submitted studies are deficient in that data for the analysis of excreta for the presence of metabolites were not submitted, and only one to three animals was used in each experimental group. The submitted data demonstrated differential effects on excretion and retention of radioactivity depending on the molecular location of the radioactive label. These findings are strong evidence that some metabolism of glyphosate occurred in rats.

These studies are not adequate to fulfill Guideline requirements (§158.135 85-1), therefore repeat studies are required.

N-Nitroso-Glyphosate

The Agency has determined that technical glyphosate contains N-nitroso-glyphosate (NNG) as a contaminant at levels of 0.1 ppm or less. The Agency has determined that oncogenicity testing of nitroso contaminants will normally be required only in those cases in which the level of nitroso compounds exceeds 1.0 ppm (see "Pesticide Contaminated with N-nitroso Compounds, proposed policy 45 FR 42854 (June 25, 1980)"). Therefore, although a chronic feeding study in rats was reviewed and found unacceptable, no additional studies are requested at this time.

Acute oral toxicity data for NNG place it in Toxicity Category III. Other acute toxicity data for NNG are not available.

Chronic toxicity studies on NNG in the dog and rat were conducted at IBT. After a raw data audit, both studies were judged to be "supplementary" (not adequate to fulfill guideline requirements). Both studies were then evaluated for scientific acceptability, and the rat study was invalid due to dosing of the control groups with an excessive amount of NaCl which resulted in high mortality of control animals. The dog study remained classified "supplementary" due to the lack of supporting raw data as identified in the raw data audit validation report. The only apparent treatment-related findings in the dog study were an increase in absolute and relative kidney weights and in blood glucose in high-dose (30 mg/kg/day) females. The NOEL for this apparent effect was 10 mg/kg/day.

A 90-day subchronic oral toxicity study with NNG was conducted in the rat. The principal effect of treatment was a dose-related decrease in survival, food consumption, and body weight gain. A NOEL was not established in this study since these effects were noted at the lowest dose tested, 3000 mg/kg/day. The study was classified as "supplementary" data due to inadequate reporting of clinical signs and necropsy data, and inadequate identification of the test material.

A rat metabolism study conducted with NNG demonstrated that NNG is rapidly absorbed and excreted, with the kidneys the preferential route of elimination. These findings are in direct contrast with the results of the metabolism studies with glyphosate, which found that absorption from the gut

was poor and the majority of excretion occurred in the feces due to unabsorbed radiolabel. Tissue residues after five consecutive doses were minimal, as no tissue contained more than 1.5 ppm of radiolabel.

No acceptable studies for mutagenic or reproductive effects are available at present for NNG.

Because the amount of N-nitroglyphosate is less than 1.0 ppm no additional toxicology data are required; therefore, none of the above studies are to be repeated or required.

Plant Metabolite--Aminomethylphosphonic Acid

The Agency has determined that the metabolite aminomethylphosphonic acid (AMPA) is formed on plants in amounts that can range as high as 28 percent of the total residue on the plant. Since the extent of glyphosate metabolism was not adequately addressed in the rat metabolism study, the possibility exists that the AMPA metabolite could pose a hazard to humans that was not evaluated by testing the parent compound glyphosate. If an acceptable rat metabolism study is submitted which demonstrates significant conversion of glyphosate to AMPA in animals, additional studies on this metabolite may be not necessary, since the toxicity of AMPA will have been assessed by chronic feeding studies with the parent compound glyphosate.

Acute oral toxicity and primary skin irritation data place AMPA in Toxicity Category IV. The primary eye irritation study demonstrated that AMPA was slightly irritating to the eye, corresponding to Toxicity Category III.

A 90-day subchronic feeding study was submitted that demonstrated irritation of the urinary bladder in rats treated with 1200 mg/kg/day, the lowest effect level (LEL) in this study. This irritation was manifested in the form of hyperplasia of the cells lining the bladder, and was noted with increased incidence and severity at the highest dose tested, 4800 mg/kg/day. Epithelial hyperplasia of the renal pelvis was also noted in high-dose rats. The NOEL for this effect was 400 mg/kg/day, and the study was classified as Core-Minimum.

A rat metabolism study demonstrated that AMPA is rapidly excreted as the parent compound. No evidence for bioaccumulation was noted in this study, which was classified as Supplementary data because the number of animals studied was not reported, only males were studied, and the effects of a minimally toxic dose and repeated nontoxic doses on excretion, metabolism, and accumulation were not assessed.

The limited data available for AMPA do not suggest that this compound poses any hazard distinct from that of the parent compound. No studies are available by which to assess potential mutagenic, reproductive, oncogenic, or chronic effects of AMPA. The need for additional testing of this compound will be assessed after the submission of an acceptable rat metabolism study with glyphosate.

Physiological and Biochemical Behavior Characteristics

Foliarly applied glyphosate is readily absorbed and translocated from treated areas to untreated shoot regions and fruits of grapes, apples, pears, dwarf citrus, and coffee, and to untreated shoots and roots of seedling almond, pecan, and walnut.

The mechanism of pesticidal action for glyphosate is believed to be inhibition of amino acid biosynthesis resulting in a reduction of protein synthesis and inhibition of growth.

The metabolism of glyphosate occurs via N-methylation and ultimately yields N-methylated glycines and phosphonic acids. In plants, degradation of [^{14}C] glyphosate to $^{14}CO_2$ and the subsequent photofixation of respired $^{14}CO_2$ was evidenced by presence of ^{14}C-residues in control plants housed in close proximity to treated plants. The parent compound and its metabolite AMPA are considered to be the residues of concern in plants. No additional plant metabolism data are required.

In animal feeding studies using nonradiolabeled glyphosate and AMPA in a 3:1 ratio, glyphosate was detected in the liver of poultry, swine, and cattle and the kidney of swine and cattle; AMPA was detected in liver of poultry, swine, and cattle and in the kidney of swine and cattle. Residues of the parent glyphosate and AMPA have also been identified in the tissues, urine, and feces of rats and rabbits. Additional metabolism studies with ruminants and poultry are required.

Environmental Characteristics

Glyphosate and its degradate aminomethylphosphonic acid are stable to hydrolysis in sterile, buffered water at pH 3, 6, and 9. In three natural waters (pH 4.2, 6.2, and 7.2) glyphosate degraded with half-lives of < 50, 63, and > 35 days, respectively. Addition of sediment to the three natural water systems increased the rate of dissipation of glyphosate from water via sorption to sediment. Glyphosate dissipated in pondwater with a half-life of between 14 and 21 days. In two canal waters, glyphosate was not detected 6 months posttreatment. Glyphosate and aminomethylphosphonic acid dissipation rates and concentrations in treated forest soils

are extremely variable ranging from < 0.002 ppm in streamwater samples to 89 ppm in foliage samples. Based on the available data that indicate that glyphosate is strongly adsorbed to the soil, the potential of glyphosate to contaminate groundwater is expected to be low. Glyphosate has the potential to contaminate surface waters because of application to aquatic sites. Glyphosate residues have a low potential to bioaccumulate in fish or clams.

Only the hydrolysis study is acceptable to fulfill Guideline requirements. The following data are required to fully assess the environmental fate of glyphosate: photodegradation studies in water, on soil, and in air; aerobic and anaerobic soil metabolism studies; aerobic and anaerobic aquatic metabolism studies; adsorption and desorption studies; laboratory volatility studies; terrestrial, forestry, and aquatic field dissipation studies; and accumulation studies on rotational, irrigated crops and fish. Additional data may be required if requested studies indicate the need for additional data.

Exposure

The primary potential for exposure from the soluble concentrate/liquid (SC/L) formulation is during mixing and loading where both dermal and ocular exposure via splashing may occur. Inhalation and dermal exposure may occur during application of liquid ready to use (RTU) and pressurized liquid (Prl) formulations. Application from aircraft increases the potential exposure of humans and nontarget organisms to glyphosate due to spray drift and volatilization.

The California Department of Food and Agricultural reported that glyphosate ranked third in the number of illnesses reported from exposure to pesticides. The majority of these illnesses were associated with skin and eye irritation during mixing, loading and application of glyphosate. Although technical glyphosate has very low toxicity (Toxicity Category III or IV) the formulated products for agricultural use cause moderate eye irritation (Toxicity Category II) and some dermal irritation (Toxicity Category III). To reduce the risk of injury to skin and eyes from use of glyphosate the Agency is requiring that "Worker Safety Rules" requiring protective clothing appear on all formulated products labeled for agricultural or aquatic use.

The end-use products registered for homeowner use are of very low concentration (0.1 to 10% active ingredient) and have very low acute toxicity (Category III and IV); therefore the Agency will not require protective clothing for these products.

Available acute dermal toxicity data place technical glyphosate and its formulated products for agricultural use in Toxicity Category III. Because of the low toxicity of glyphosate materials as applied, the Agency believes that there is no risk of acute injury to field workers from applications of glyphosate. Therefore reentry data will not be required by the Agency.

Ecological Characteristics

Terrestrial Organisms

Based on an acute oral toxicity of > 2000 mg/kg/day for bobwhite quail, glyphosate is no more than slightly toxic to bobwhite quail on an acute oral basis. Available data indicate that the 8-day dietary toxicity of glyphosate is > 4000 ppm for both mallard ducks and bobwhite quail. Based on the forgoing data, the Agency has determined that glyphosate is no more than slightly toxic to birds. Avian reproduction studies indicate reproductive impairment would not be expected at dietary levels up to 1000 ppm. Glyphosate is relatively nontoxic to honeybees. Available data indicate that the 48-hour acute toxicity to honeybees is > 100 micrograms per bee.

Aquatic Organisms

Based on a 48-hour acute toxicity of 780 ppm for Daphnia magna, technical glyphosate is no more than slightly toxic to aquatic invertebrates. Three tests on warmwater species, one bluegill and two fathead minnow, produced the 96-hour toxicities of 120 ppm, 84 mg/L and 97 mg/L, respectively; two rainbow trout 96-hour toxicities of 86 mg/L and 140 mg/L. These data indicate that glyphosate is no more than slightly toxic to freshwater species.

In addition to the acute studies a fish lifecycle study showed no effects at 25.7 mg/L, the highest level tested, indicating that glyphosate has a maximum acceptable threshold concentration (MATC) greater than 25.7 mg/L. A Daphnia study with MATC between 50 and 96 mg/L reported reduced reproductive capacity, the most sensitive parameter.

A series of studies was performed on marine/estuarine species. A 96-hour toxicity of 281 mg/L was found for grass shrimp. In a study on fiddler crabs, it was determined that 96-hour toxicity is 934 mg/L glyphosate. Both of these studies indicate that glyphosate is no more than slightly toxic. An embryolarvae 48-hour acute toxicity test indicated that glyphosate is no more that moderately toxic.

Plant Protection

No studies were evaluated under this type.

Tier 1 testing is required on a case-by-case basis to support (I) products for which phytotoxicity problems arise and open literature data are not available (II) products that may pose hazards to endangered or threatened species. Since glyphosate has use patterns similar to those chemicals that have jeopardy opinions prepared by Office of Endangered Species (OES), the Agency is assuming that use of glyphosate may also pose hazards to endangered plants. The Agency is requiring that Tier 1 testing be performed with glyphosate. Refer to charts in Appendix I for testing required.

Endangered Species

In considering the hazard to endangered species the previous consultations with the OES were reviewed. The Endangered Species Act requires all federal agencies to formally consult with OES whenever an action taken by them may affect an endangered species. The consultation provides an opinion which may or may not indicate hazard to an endangered species. An opinion which indicates hazard is a jeopardy opinion. Consultations on crops (alfalfa, apples, barley, corn, cotton, pears, and wheat), rangeland/pastureland, and silvicultural sites has resulted in jeopardy opinions relating to glyphosate. In order to protect the jeopardized species, the Agency will require additional product labeling

The consultation for the crop cluster indicated jeopardy for Solano grass, Houston toad, and the Valley elderberry longhorn beetle. Glyphosate products with crop uses are required to bear the labeling entitled, "Glyphosate Endangered Species Labeling (crop sites)." Refer to Section D of Part IV for label wording.

Silviculture sites were addressed under the forest cluster. The following plant species were identified to be at risk: green pitcher plant, Chapman rhododendron, Florida torreya, hairy rattleweed, persistent trillum, small-whorled pogonia, northern wild monkshood, Furbish lousewort, mountain golden-heather, and Virginia round-leaf birch. Glyphosate products with silvicultural uses are required to bear the labeling entitled "Glyphosate Endangered Species Labeling (Silvicultural Sites)." Refer to Section D of Part IV for label wording.

The OES has indicated jeopardy for the following plants when rangeland/pastureland is treated with herbicides: green pitcher plant, Arizona agave, Nichol's Turk's head cactus, Arizona hedgehog cactus, Brady pincushion cactus, Peebles Navajo cactus, Siler pincushion cactus, Arizona cliffrose, Carex specuicola, Thornber's fishhook cactus, large-flowered

fiddleneck, San Benito evening-primrose, salt marsh birds-beak, San Clemente Island Indian paintbrush, San Clemente Island larkspur, Eureka dune grass, Solano grass, Antioch Dunes evening-primrose, San Clemente Island bush-mallow, San Diego mesa mint, San Clemente Island broom, Raven's manzanita, Santa Barbara Island liveforever, Pedate checker-mallow, slender-petaled mustard, Contra Costa wallflower, McDonald's rockcress, Truckee barberry, Uinta Basin hookless cactus, Mesa Verde cactus, North Park phacelia, clay-loving wild-buckwheat, purple-spined hedgehog cactus, knowlton cactus, spineless hedgehog cactus, Clay phacelia, Hairy rattleweed, Nehe, Harper's beauty, Miccosukee gooseberry, Gouania hillebrandii, Stenogyne angustifolia var. angustifolia, Haplostachys haplostachya var. angustifolia, Ewa Plains' akoko, Diamond Head schiedea, Liochaeta venosa, caneate bidens, MacFarlane's four-o'clock, Short's goldenrod, Robbins cinquefoil, Lee pincushion cactus, Sneed pincushion cactus, Kuenzler hedgehog cactus, McKittrick pennyroyal, Todsen's pennyroyal, gypsum wild-buckwheat, Rhizome fleabane, Cirsium vinaceum, bunched arrowhead, Malheur wire-lettuce, Tennessee purple coneflower, Ashy dogweed, Tobusch fishhook cactus, Nellie cory cactus, bunched cory cactus, Lloyd's hedgehog cactus, black lace cactus, Davis' green pitaya, Lloyd's mariposa cactus, Johnston's frankenia, Texas poppy-mallow, Texas snowbells, Novasota ladies'-tresses, Texas wild-rice, Maguire daisy, Wright fishhook cactus, Rydberg milk-vetch, Dwarf bear-poppy and Last Chance townsendia. As a result of this consultation, glyphosate products with uses for range and pastureland are required to bear the labeling entitled "Glyphosate Endangered Species Labeling (Range and Pastureland Uses)." Refer to Part D of Section IV for label wording.

Endangered species labeling may be required for aquatic and noncrop uses when the respective generic consultations from Office of Endangered Species are available.

The following registered uses of glyphosate have not been reviewed in the cluster project or in registration submissions: almond, apricot, artichoke (Jerusalem), asparagus, avocado, banana, beans, beet greens, beets (red), bermudagrass (seed crop), broccoli, cabbage, carrot, cauliflower, celery, cherry, chicory, citrus, coffee, cranberry, filbert, gardens, grapes, grasses grown for seed, guava, horseradish, kale, lentils, lettuce, macadamia nuts, mango, mustard greens, nectarine, okra, onions, papaya, parsnips, peachs, peanuts, peas, pecans, pineapple, pistachio, plum, potato (irish), prune, radish, rutabaga, spinach, sugar beets, sugarcane, sweet potato, tea, turnips, walnut, watercress, and ornamentals.

Tolerance Reassessment

Tolerances have been established for residues of glyphosate in a variety of raw agricultural commodities, in meat, fat, and meat byproducts (40 CFR 180.364) and in processed food (21 CFR 193.235) and feed (21 CFR 561.253). EPA has evaluated the residue and toxicology data supporting tolerances, and has addressed the following questions:

a. Whether the available data support all currently registered use patterns (including those registered under FIFRA section 24(c) and intrastate uses and methods of application).

b. Whether the existing uses of glyphosate require the establishment of tolerances in animal products because of residues that may transfer to animals from feed items derived from raw agricultural commodities.

c. Whether food additive regulations are necessary because residues in the raw agricultural commodity concentrate in processing.

d. Whether group tolerances could be established in accordance with 40 CFR 180.34(f).

e. Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

f. Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in Section IV A, Regulatory Positions and Rationales.

Residue Data

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of glyphosate. Available data indicate that the major metabolite of glyphosate is aminomethylphosphonic acid (AMPA). The established tolerances are based on occurrence of glyphosate and AMPA in plants and animals.

b. Radiolabeled studies on the uptake, translocation, and metabolism of glyphosate in plants which show that the parent compound, glyphosate, and its metabolite, AMPA, are the residues of concern in plants.

c. Radiolabeled studies on the uptake, translocation, and metabolism of glyphosate in poultry, swine, cattle, rats, and rabbits which show that glyphosate and its metabolite, AMPA, occur in liver of poultry, swine, and cattle and kidney of swine and cattle. These residues have also been identified in the tissues, urine, and feces of rats and rabbits.

d. Analytical methodology for determining levels of residues of glyphosate in plants, animals, and water. The available gas liquid chromatography (GLC) method for analysis in milk, eggs, and animal tissues is adequate for data collection and enforcement. Available methods for analysis of residues of glyphosate and its major metabolite, AMPA, in or on plant commodities or water are adequate for data collection.

e. Storage stability data demonstrating residues of glyphosate. Available data are sufficient to ascertain that residues of glyphosate and its AMPA metabolite are stable in or on frozen plant products for up to 7 months. No data were submitted concerning storage stability of glyphosate in or on animal products (tissue, milk, or eggs) or water.

f. Data on magnitude and levels of residues of glyphosate in individual raw agricultural commodities, animal products, and processed food and feed items.

Toxicology Data

The toxicology data considered in support of the tolerances include: a chronic feeding study in mice with a NOEL of 5000 ppm; a chronic feeding study in rats with a NOEL greater than 31 mg/kg/day; a rat teratology study with a fetotoxic and maternal NOEL of 1000 mg/kg/day and no observed teratogenic effects; a rabbit teratology study with a maternal toxicity NOEL of 175 mg/kg/day, a fetotoxicity NOEL of 350 mg/kg/day and no observed teratogenic effects; a three-generation reproduction study in rats with a NOEL of 10 mg/kg/day; and

several mutagenicity studies, all negative. Refer to the toxicology section above for detailed information on available data and additional requirements.

The acceptable daily intake (ADI) for glyphosate is currently based on the finding of renal tubular dilation in F_{3b} pups in the rat three-generation reproduction study. The NOEL for this effect was 10 mg/kg/day. Using a hundred-fold safety factor, the ADI for glyphosate is 0.1 mg/kg/day, which is equivalent to a maximum permissible intake (MPI) of 6.0 mg/day in a 60-kg individual. Existing tolerances produce a theoretical maximum residue contribution (TMRC) of 1.4238 mg/day from a 1.5 kg diet which occupies 23.73 percent of the ADI.

Tolerances Issued

Refer to 40 CFR 180.364, 21 CFR 193.235, and 21 CFR 561.253 for tolerances established on glyphosate and its metabolite aminomethylphosphonic acid.

Canadian tolerances have been established for residues of glyphosate in or on carrots, sugar beets, lettuce, cabbage, beans, peas, soybeans, citrus, pome fruits, stone fruits, grapes, cereals, grasses, and forage legumes at 0.1 ppm.

No Mexican or Codex tolerances have been established for glyphosate.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITION AND RATIONALE

1. None of the risk criteria listed in 40 CFR 154.7 have been exceeded for glyphosate. Therefore, no referral to Special Review is being made at this time. The Agency is requiring a repeat of the mouse and rat oncogenicity studies.

Rationale: A review of the data indicates no risk criteria have been exceeded or met. A review of the mouse oncogenicity study noted a slight increase in the incidence of renal tubular

adenomas. Based on reviews by the Toxicology Branch Ad Hoc Oncogenicity Committee and the Science Advisory Panel, the Agency concluded that the mouse study was not adequate to define the oncogenic potential of glyphosate. A review of the rat oncogenicity study determined that a maximum tolerated dose had not been reached; therefore, the rat study was also inadequate to determine oncogenic potential. Refer to Part III - Agency Assessments for detailed discussion of data.

2. The Agency will issue registrations for substantially similar products and will issue significant* new uses on a case-by-case basis.

Rationale: The available data do not clearly demonstrate whether glyphosate is an oncogen. However, even if it is assumed to be an oncogen, the data suggests that it would be relatively weak. Pending completion and review of the required chronic feeding studies the Agency would use the Q* from the existing mouse study and other relevant data in assuming the potential risk from addition of any significant new use.

3. The Agency is not imposing a ground water advisory statement for glyphosate.

Rationale: Available data indicate that glyphosate is strongly adsorbed to the soil; therefore, the potential of glyphosate to contaminate ground water is expected to be low. Refer to the Environmental Characteristics Section of Part III - Agency Assessments for a detailed discussion of available data.

4. The Agency is not imposing any reentry statements nor is it requesting that reentry data be submitted.

Rationale: Available acute dermal toxicity data place technical glyphosate and its formulated products for agricultural use in Toxicity Category III. Based on glyphosate's low acute toxicity and the fact that the major routes of exposure are via splashing during mixing and loading, it is not expected that field workers would be exposed to acutely toxic levels of glyphosate following agricultural treatments. Therefore, reentry data or intervals are not required by the Agency.

5. The Agency is requiring that labeling on all end-use products except those labeled for homeowner use only bear "Worker Safety Rules" requiring protective clothing requirements (face shield or goggles), chemical resistant

*Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in Theoretical Maximum Residue Contribution of greater than 1 percent.

gloves, chemical resistant apron and chemical resistant shoes, shoe coverings, or boots). Refer to Section D of Part IV for detailed wording.

Rationale: The major routes of exposure are dermal and ocular via splashing during mixing or loading. Exposure to all formulations of glyphosate during application is expected to be dermal. Information from the California Department of Food and Agriculture reported incidents of worker poisonings or illnesses due to skin or eye irritation. Although technical glyphosate has very low toxicity (not irritating), formulations of glyphosate for agricultural use cause moderate eye irritation and some dermal irritation. The "Worker Safety Rules" required will reduce the exposure of workers to formulations of glyphosate. The formulated products labeled for homeowner uses only are of very low concentration and available data show they are not very irritating to either skin or eyes.

6. The Agency is imposing endangered species labeling for crops (alfalfa, apples, barley, cotton, pears, and wheat), rangleland and pastureland, and silvicultural sites. Refer to Section IV D for labeling requirements.

Rationale: Consultations with the Office of Endangered Species resulted in jeopardy opinions for several species (refer to Endangered Species Section of Part III for lists of species). The proposed labeling is intended to reduce the hazard to endangered or threatened species.

7. The Agency is imposing a label restriction prohibiting the rotation of food or feed crops in glyphosate treated soils unless glyphosate is registered for use on those crops. This restriction will be in effect until the requested rotational crop data are submitted and reviewed. Refer to Section IV Part D for exact wording.

Rationale: Rotational crop data are unavailable for glyphosate. Therefore the Agency cannot determine a length of time after treatment of soil with glyphosate that food or feed crops may be planted without exposure to residues of glyphosate. This statement is to ensure that food or feed crops without tolerances are not exposed to residues of glyphosate.

8. The Agency is imposing a label restriction prohibiting the use of glyphosate on rice fields in which crayfish and catfish are included in cultural practice.

Rationale: Tolerances are not established for residues of glyphosate in crayfish and catfish. This restriction is to ensure that crayfish and catfish harvested for human food are not exposed to residues of glyphosate.

9. The Agency is imposing label restrictions prohibiting the use of water containing glyphosate from rice cultivation for irrigation of feed or food crops not appearing on glyphosate labels.

Rationale: Data are not available to support the use of water containing glyphosate for irrigation purposes on feed or feed crops not appearing on the label. These restrictions are to ensure that food or feed crops not having tolerances are not exposed to residues of glyphosate.

10. The Agency will not require additional residue data on the following raw agricultural commodities: garden beets; carrots; potatoes; rutabagas; sugar beets; sweet potatoes; garden beet tops; chicory tops; sugar beet tops; celery; lettuce; spinach; cauliflower; kale; mustard greens; dried beans; lentils; lima beans; peas (succulent or dried); snap beans; soybeans; bean vines and hay; lentil forage and hay; soybean forage and hay; grapes; barley grain; corn grain (including popcorn), and sweet corn (kernels plus cob with husks removed); oat grain; rice grain; wheat grain; barley forage, hay, and straw; corn forage, silage, and fodder; oat forage, hay, and straw; rice straw; wheat forage, hay, and straw; avocados; bananas (including plantains); cotton; guava; okra; papayas; pineapple; pistachionuts; and watercress. Additional residue data are not required for the following processed food or feeds: soybean hulls, almond hulls, barley milled products, oat milled products; and sugarcane molasses. Additional residue data are not required for the following crop groupings: legume vegetables; foliage of legumes vegetables group; pome fruits group; treenuts; grass forage; fodder and hay group; and forage and hay of nongrass animal feeds.

Rationale: The Agency has determined that the available residue data adequately support the established tolerances for these raw agricultural commodities, foods, feeds, and crop groups.

11. The Agency is requiring that additional residue data and/or information be submitted on the following raw agricultural commodities: parsnips; turnips, turnip greens; onions; cranberries; sorghum grain; asparagus; coffee; mangos; peanuts,

peanut forage, hay, and hulls; and sugarcane. Additional residue data and/or information are required on the following processed foods or feeds; potato granules, chips and dried potatoes; processed commodities of sugar beets (dehydrated pulp, molasses, and refined sugar); dried citrus pulp; prunes; processed products of grapes; corn oil (crude and refined); corn-milled products; processed products of grain and sorghum; wheat-milled products; alfalfa seed; and processed olives, and olives. Additional residue data and/or information are required on the following crop groups: root and tuber vegetables; leaves of root and tuber vegetables, bulb vegetables groups; leafy vegetables (except brassica vegetables group, brassica leafy vegetables group; fruiting vegetables (except cucurbits) group; citrus fruits group; small fruits and berries group; and cereal grains group. Refer to the data tables in Appendix I for a detailed discussion of types of data and/or information needed.

Rationale: The Agency has determined that the available residue data do not adequately support the established tolerances for these raw agricultural commodities, foods, feeds and crop groups.

12. The Agency requires residue data together with a petition for establishing tolerances, if necessary, for sugarcane forage and pineapple forage. Alternatively, a statement may be placed on the label restricting the grazing or feeding of treated commodities. Each registrant will have 6 months to notify the Agency which alternative it chooses. Refer to the data tables in Appendix I for details of residue data required.

Rationale: Review of available data indicates that residue data are required to determine whether residues are transferred to animals from feed items. A grazing restriction prevents the transfer of residues from animals to feed items.

13. The Agency intends to disapprove the registrations of the following 24(c) registrations (KS820001, MO820014, NE820009, NM820001, OK820010, and TX820023. Alternatively, residue data and petitions for tolerances must be submitted proposing tolerances on sorghum forage, fodder, and hay reflecting these uses. Each registrant will have 6 months to notify the Agency which alternative he chooses. Refer to the data tables in Appendix I for details of the residue data required.

Rationale: Available residue data do not support this use pattern.

14. The Agency is requiring the following changes in the tolerance listings.

a. The tolerance for residues in or on root crop vegetables should be deleted and individual tolerances established or proposed for individual members of the root and tuber vegetables crop group.

b. The tolerance for residues in or on seed and pod vegetables should be deleted and individual tolerances established for members of the former seed and pod vegetables group on which use of glyphosate is registered.

c. The entry "Nuts" will be amended read "Tree Nuts."

d. The tolerance for residues in or on leafy vegetables should be deleted and tolerances established for residues in or on individual members of the leafy vegetable crop group.

e. The existing tolerances for alfalfa, clover, and forage legumes should be deleted and separate tolerances for residues of glyphosate and AMPA of 100 ppm should be established for residues of forage and hay of nongrass animal feeds.

f. The existing tolerance for residues in or on forage legumes should be deleted and separate tolerances of 0.2 ppm should be established in or on legume vegetables (except soybeans) and the foliage of legume vegetables, except soybean forage and hay.

g. The established tolerances for forage grasses, grasses, forage, Bahiagrass, bermudagrass, bluegrass, bromegrass, fescue, orchardgrass, ryegrass, timothy and wheat grass should be deleted and a separate tolerance of 100 ppm for residues in or on grass forage and hay must be established.

Rationale: The crop groupings as listed have been superseded by publication of new crop groupings. (Refer to 40 CFR 180.34.

15. The tolerance for cottonseed forage and hay must be cancelled.

Rationale: These tolerances are inappropriate because cotton hay is not fed to animals; therefore, hay is not considered a raw agricultural commodity of cotton. Since a grazing restriction prohibits feeding of cotton forage, no residues are transferred to animals from the feed item cotton forage.

16. The food additive tolerances for instant tea from imported dried tea will be raised from 4 ppm to 7 ppm.

Rationale: The available processing data indicate that residues of glyphosate concentrating in the processed commodity instant tea are 5 to 7 times more than in the processed commodity imported dried tea. Available data support the established tolerance of 1 ppm on imported dried teas.

17. The Agency is requiring additional data on crops treated with irrigation water containing residues of glyphosate. Once these data are submitted, the crop groupings presently listed in § 180.364(c) must be deleted and tolerances based on the requested field irrigation tests must be established for glyphosate residues in or on members of the current, appropriate crop groups and all major irrigated crops which are not included in a crop group, such as cottonseed, sugarcane, peanuts, etc.

Rationale: Available data are not sufficient to determine the magnitude of glyphosate residues in or on crops treated with irrigation water containing residues of glyphosate.

18. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing glyphosate as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain glyphosate as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MP's) must contain glyphosate as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing glyphosate provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

D. REQUIRED LABELING

All MPs (and EPs if covered by Standard) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements. All labeling changes must appear on all products in channels of trade by June 30, 1988.

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for MP's must list the active ingredient as:

Glyphosate, N-phosphonomethyl glycine

2. Precautionary Statements

Statements for Manufacturing-Use Products

> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES* permit. Do not discharge effluent

*National Pollution Discharge Elimination System.

containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Statements for End-Use Products

Outdoor Uses

Products not labeled for aquatic use

Do not apply directly to water or wetland (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of waste.

Products Labeled for Aquatic Use

Do not contaminate water by cleaning of equipment or disposal of waste. Treatment of aquatic weeds can result in oxygen loss from decomposition for dead plants. This loss can cause fish suffocation.

3. The following label statements must appear on all end-use products.

Rotational Crop

Do not use glyphosate on rice fields in which crayfish and catfish farming are included in the cultural practice and do not plant crops other than those with registered glyphosate uses for food or feed in glyphosate-treated soil.

Irrigated Crops

Do not use water containing glyphosate residues from rice cultivation to irrigate food or feed crops not listed on the glyphosate label.

4. The following Worker Safety Rules must appear on end-use products containing glyphosate except for those labeled for homeowner use only.

Worker Safety Rules

THIS PRODUCT CAUSES EYE IRRITATION AND SKIN IRRITATION

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes with hands. If you feel sick in any way, STOP work and get help right away. See First Aid (Practical Treatment) section.

HANDLE THE CONCENTRATE ONLY WHEN WEARING THE PROTECTIVE CLOTHING AND EQUIPMENT.

Wear goggles or a face shield, chemical-resistant gloves, chemical resistant apron, and chemical-resistant shoes, shoe coverings, or boots.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, CLEANING, DISPOSAL OF THE PESTICIDE SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS BEFORE THE SPRAY HAS DRIED.

Wear goggles or a face shield, chemical-resistant gloves and chemical-resistant shoes, shoe covers, or boots. A helmet with visor may be worn during open cockpit aerial application.

During application only from a tractor with a completely enclosed cab or aerially with an enclosed cockpit the above protective clothing is waived. Chemical-resistant gloves must be available in the cab or cockpit and must be worn while exiting.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, wash protective clothing and protective equipment with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with State and local regulations.

HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

5. The following Endangered Species labeling is required for all end-use products labeled for the following use patterns.

Glyphosate products with silviculture uses are required to bear the following labeling:

Glyphosate Endangered Species Labeling
(Silvicultural Sites)

ENDANGERED SPECIES RESTRICTIONS

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of Federal law. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

Before using this pesticide in the following counties you must obtain the EPA Forest Herbicide Endangered Species Bulletin (EPA/ES-FOREST). The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The Forest Herbicide Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the appropriate Regional Office of either the U.S. Fish and Wildlife Service (FWS) or the U.S. Environmental Protection Agency (EPA) indicated below. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

Contact FWS or EPA in Atlanta, Georgia

ALABAMA: counties of Cherokee, DeKalb, Marshall, Jackson, and Etowah

FLORIDA: counties of Clay, Gadsden, Gulf, Liberty, and Jackson

GEORGIA: counties of Decatur, Towns, Wayne, Brantley, Rabun, Habersham, and Stephans

NORTH CAROLINA: counties of Burke, Macon, and Henderson

SOUTH CAROLINA: Oconee county

Contact FWS in Newton Corner, Massachusetts or EPA in Philadelphia, Pennsylvania

NEW JERSEY: Sussex county

PENNSYLVANIA: counties of Venango and Centre

VIRGINIA: counties of Smyth, Caroline, and James City

Contact FWS in Newton Corner, Massachusetts or EPA in Boston, Massachusetts

MAINE: counties of Arrostook, Cumberland, and Kennebec

MASSACHUSETTS: counties of Hampshire and Essex

NEW HAMPSHIRE: counties of Strafford, Belknap, Merrimack, Rockingham, and Carroll

RHODE ISLAND: Providence county

Glyphosate products with uses for rangeland and pastureland are required to bear the following labeling:

Glyphosate Endangered Species Labeling (Rangeland and Pasture Uses)

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of Federal law. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

Before using this pesticide in the following counties you must obtain and review the EPA Rangeland and Endangered Species Bulletin (Bulletin EPA/ES-RANGE). The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The Rangeland Bulletin is available from your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the appropriate Regional Office of the Wildlife Agency Headquarters or the appropriate Regional Office of the U.S. Fish and Wildlife Service (FWS) or the U.S. Environmental Protection Agency (EPA) indicated below. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

Contact FWS in Portland, Oregon or EPA in San Francisco, California

CALIFORNIA: counties of San Benito, Monterey, San Luis Obispo, Fresno, Kings, Kern, Santa Barbara, Ventura, Tulare, San Joaquin, San Diego, Los Angeles, Inyo, Solano, San Francisco, San Bernardino, Contra Costa, Mendocino, and Nevada

HAWAII: Island of Maui, District of Lahaina, Island of Hawaii, and Island of Oahu

Contact FWS in Portland, Oregon or EPA in Seattle, Washington

IDAHO: Idaho county

OREGON: counties of Harney and Wallowa

Contact FWS in Albuquerque, New Mexico or EPA in San Francisco, California

ARIZONA: counties of Yavapai, Maricopa, Pinal, Pima, Gila, Navajo, Mohave, and Graham

Contact FWS in Albuquerque, New Mexico or EPA in Dallas, Texas

NEW MEXICO: counties of Eddy, Dona Ana, Otero, Chaves, Lincoln, San Juan, Sierra, McKinley, and Catron

TEXAS: counties of El Paso, Culberson, Zapata, Bandera, Kerr, Brewster, Terrell, Pecos, Jim Wells, Kelburg, Refugio, Starr, Runnels, Edwards, Real, Kimble, Val Verde, Brazos, and Hays

Contact FWS or EPA in Atlanta, Georgia

ALABAMA: counties of Cherokee, De Kalb, Jackson, and Marshall

FLORIDA: counties of Franklin, Liberty, and Jefferson
GEORGIA: counties of Towns, Wayne, and Brantley

KENTUCKY: counties of Nicholas, Fleming, and Robertson

NORTH CAROLINA: Henderson county

SOUTH CAROLINA: counties of McCormick and Greenville

TENNESSEE: counties of Rutherford, Wilson, and Davidson

Contact FWS or EPA in Boston, Massachusetts

NEW HAMPSHIRE: Coos county

Contact FWS or EPA in Denver, Colorado

COLORADO: counties of Delta, Mesa, Montrose, Montezuma, Jackson, Washington, La Plata, and Duray

UTAH: counties of Washington, San Juan, Duchesne, Summit, Emery, Wayne, Piute, Garfield, Utah, and Sevier

Glyphosate products labeled for use on field crops (corn, cotton, soybeans, sorghum, small grains, alfalfa, and for apples and pears) must bear the following label:

[GLYPHOSATE (LABELING INFORMATION FOR FIELD CROP USES: CORN, COTTON, SOYBEANS, SORGHUM, SMALL GRAINS, ALFALFA, AND FOR APPLES AND PEARS)]

ENDANGERED SPECIES RESTRICTIONS

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of Federal law.

The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range:

STATE Species (BULLETIN NO.)	County		
	Corn Cotton Wheat Barley Pears Apples	Soybeans Sorghum	Alfalfa
CALIFORNIA Solano grass (EPA/ES-85-13)	SOLANO		
Valley elderberry longhorn beetle (EPA/ES-85-08)	MERCED		
TEXAS Houston toad (EPA/ES-85-28)	BURELSON BASTROP	HARRIS	

Before using any pesticide in the above counties you must obtain the EPA Bulletin specific to your area. The use of this pesticide is prohibited in the above-named counties unless specified otherwise in the Bulletins. The EPA Bulletins are available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters, or the appropriate Regional Office of the U.S. Fish and Wildlife Service or the U.S. Environmental Protection Agency. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data, and either--

(a) Submit the existing data that you believe will satisfy the data requirements, or

(b) State that you will secure the data or have made a contract to have any necessary studies completed within the applicable time period.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not automatically extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not automatically extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you plan to submit the data, and think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not automatically extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

EPA will permit continued sale and distribution of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act. However, the Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may issue a Notice of Intent to Cancel the registration of your product under FIFRA sec. 6(b)(1).

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Products (MUPs) containing Glyphosate as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form).

d. Product Specific Data Report (EPA Form 8580-4).

e. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 12 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any required product-specific data (See Table B or C).

b. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Glyphosate in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Glyphosate alone or in or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

d. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

2. Within 12 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Glyphosate either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor (PM-25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

Guide to Tables

Table A

Table B

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes[2/3/]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes[4/]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	N/A	Yes[5/]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]		Must Additional Data be Submitted?	Timeframe for Submissio
§158.120 Product Chemistry - Continued							
Physical and Chemical Characteristics (Continued)							
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A		Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	No	N/A		Yes	6 Months
63-9 - Vapor Pressure	PAI	All	No	N/A		Yes	6 Months
63-10 - Dissociation constant	PAI	All	No	N/A		Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No	N/A		Yes	6 Months
63-12 - pH	TGAI	All	No	N/A		Yes	6 Months
63-13 - Stability	TGAI	All	No	N/A		Yes	6 Months
63-17 - Storage Stability	PAI	A,C	Partially	00039142 00040083 00051980 00053002	00061553 00061555 00108129 00108102	Yes[6/]	15 Months
Other Requirements							
64-1 - Submittal of samples	TGAI, PAI	All	No	N/A		Yes	6 Months

§158.120 Product Chemistry - Continued

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Details of the manufacturing process, including the relative amounts of beginning materials, a description of equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures for 41.04% formulation intermediate (FI), the 53.5% FI, the 62% FI, the unregistered technical isopropylamine glyphosate salt product used to produce the FI's, and the unregistered technical trisodium salt are required.

3/ The name and address of manufacturer, producer, or supplier of each beginning material used to manufacture the 41.04% FI, the 53% FI, the unregistered technical products to produce the FIs and the unregistered trisodium salt are required. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes the composition and properties must be submitted.

4/ A discussion of each impurity believed to be present at 0.1% or more based on knowledge of the beginning materials, all possible chemical reactions and any contamination are required for the 41.04% FI, the 53.5% FI, the 62% FI, and the technical trisodium salt.

5/ Five or more representative samples of the 41.04% FI, the 53.5% FI, the 62% FI, and the unregistered technical trisodium salt analyzed for the amount of active ingredient and each impurity present at 0.1% (w/w) (including any nitroso-amines which may be present at ~0.1 ppm) are required.

6/ No data were submitted concerning the storage stability of glyphosate in or on animal products (tissue, milk, eggs) or water. The following additional data are required:

- The storage intervals and conditions of storage of plant, animal, and water samples used to support all established tolerances (ARLOW for water), for residues in or on these commodities must be submitted. These data must be accompanied by data depicting the percent decline in residues at the times and under the conditions specified. (No additional stability studies are required for plant commodities stored frozen for < 7 months.) On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

- All residue data requested in this standard must be accompanied by data regarding storage length and conditions of storage must be analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified, with the exception of plant commodities stored frozen for < 7 months.

- If the requested metabolism data reveal the presence of metabolites of toxicological concern other than glyphosate and aminomethylphosphonic acid (AMPA), additional data depicting the stability of such metabolites will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	No		Yes	6 Months
171-3 - Directions for Use	--	Yes	Product Label	No	
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Yes	00038771 00108133 00039141 00108140 00051983 00108151 00065753 00111945 00108097 GS0178-003 00108129	No	
- Livestock	PAIRA and Plant Metabolites	Partially	00094971 00108101 00108098 00108116 00108099 00108200 00108100 GS0178-004	Yes[1/]	18 Months
171-4 - Residue Analytical Method					
- Plants	TGAI and Metabolites	Yes	00028853 00078823 00036223 00078824 00037688 00108144 00038770 00108149 00044423 00108151 00051982 00108175 00053002 00108176 00053005 00108186 00060103 00111945	No[2/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residence Chemistry - Continued					
171-4 - Residence Analytical Method - Continued					
- Plants - Continued					
			00061559 00111949 00063714 00122715 00065751 GS0178-019 00065752 GS0178-020 00067425 GS1278-021 00076805 GS0178-022		
- Animals	TGAI and Metabolites	Partially	00036231 GS1278-014 00038979 GS0178-023	Yes	18 Months
- Water	TGAI and Metabolites	Yes	00036222 00108231 GS0178-017	No	

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue Residue Studies for Each Food Use					
Root and Tuber Vegetables Group[3]					
- Beets, garden	TEP	Yes	00108159	No[4]	
- Carrots	TEP	Yes	00108159	No[4]	
- Radishes	TEP	Yes	00108159	No[4]	
- Potatoes	TEP	Yes	00108151	No[4]	
- Processed Potato Commodities (Granules, Chips, Dried Potatoes)	EP	No		Yes[5]	24 Months
- Rutabagas	TEP	No		No[6]	
- Parsnips	TEP	No		Yes[4/7]	18 Months
- Sugar beets	TEP	Yes	00039381 00108151	No[4]	
- Processed Sugar beet Commodities (dehydrated pulp, molasses, refined sugar)	EP	No		Yes[8]	24 Months
- Sweet potatoes	TEP	Yes	00108151	No[4]	
- Turnips	TEP	No		Yes[9]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
Leaves of Root and Tuber Vegetable Group[10]					
- Beet tops, garden	TEP	No		No[11]	
- Chicory tops	TEP	No		No[11]	
- Sugar beet tops	TEP	Yes	00039381 00108151	No[4/11]	
- Turnip greens	TEP	No		Yes[11/12]	18 Months
Bulb Vegetable Group[13]					
- Onions	TEP	No		Yes[14]	18 Month
Leafy Vegetables (except Brassica vegetables) Group[15]					
- Celery	TEP	No		No[16/17]	
- Lettuce	TEP	Yes	00108159	No[16]	
- Spinach	TEP	No		No[16/18]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submissior
§158.125 Residue Chemistry - Continued					
Brassica Leafy Vegetable Group[19/]					
- Cabbage	TEP	Yes	00108159	No[20/]	
- Cauliflower	TEP	No		No[20/21/]	
- Kale	TEP	No		No[20/22/]	
- Mustard greens	TEP	No		No[20/23/]	
Legume Vegetables (succulent or dried) Group[24/]					
- Dried beans	TEP	Yes	00108159	No[25/]	
- Lentils	TEP	Yes	00108159	No[25/]	
- Lima beans	TEP	Yes	00108159	No[25/]	
- Peas (succulent or dried)	TEP	Yes	00108159	No[25/]	
- Snap beans	TEP	Yes	00108159	No[25/]	
- Soybeans	TEP	Yes	00015759 00015767 00015760 00024503 00015761 00033954 00015762 00038908 00015763 00040084	No	

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
- Soybeans - continued			00015764 00061555 00015765 00108153 00015766 00108203		
- Soybean hulls	EP	Yes	00015759 00015767 00015760 00024503 00015761 00033954 00015762 00038908 00015763 00040084 00015764 00061555 00015765 00108153 00015766 00108203	No	
- Soybean soapstock	EP	No		Yes[26/]	24 Months
Foliage of Legumes Vegetable Group[27/]					
- Bean vines and hay	TEP	Yes	00108159	No[28/]	
- Lentil forage and hay	TEP	Yes	00108159	No[28/]	
- Soybean forage and hay	TEP	Yes	00015759 00015767 00015760 00033954 00015761 00038908 00015762 00040084 00015763 00061555 00015764 000108153 00015765 000108203 00015766	No	

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
Fruiting Vegetables (except cucurbits) Group[29/]					
Cucurbits Vegetables Group[30/]					
Citrus Fruits Group	TEP	Partially	00039142	Yes[31/]	18 Months
- Dried citrus pulp	EP	No		Yes[31/]	24 Months
Pome Fruits Group	TEP	Yes	00108129	No	
Stone Fruits Group[32/]	TEP	Partially	00111949	Yes	18 Months
- Prunes	EP	No		Yes[33/]	24 Months
Small Fruits and Berries Group[34/]					
- Blackberries[35/]					
- Blueberries[35/]					
- Cranberries	TEP	Partially	00053002	Yes[36/]	18 Months
- Grapes	TEP	Yes	00038770 00108132	No	
- Processed products of grapes	EP	No		Yes[37/]	24 Months
- Raspberries[35/]					
- Strawberries[35/]					

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
Tree Nuts	TEP	Yes	00111945	No	
- Almond hulls	EP	Yes	00111945	No	
Cereal Grain Group[38/]					
- Barley grain	TEP	Yes	00038908 00040087 00044422 00108203	No[39/]	
- Barley milled products	EP	No		No[40/]	
- Corn grain (including popcorn) and sweet corn (kernels plus cob with husks removed)	TEP	Yes	00023336 00040085 00023512 00048284 00037687 00108203 00038908	No[39/]	
- Corn oil (crude and Refined)	EP	No		Yes[41/]	24 Months
- Corn milled products	EP	No		Yes[41/]	24 Months
- Oat grain	TEP	Yes	00038908 00040087 00044422 00108203	No	
- Oat milled products	EP	No		No[42/]	

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
- Rice grain	TEP	Yes	00038908 00040087 00044422	No[39/]	
- Sorghum grain	TEP	Partially	00038908 00040087 00044422 00108203 00109271	Yes[43/]	18 Months
- Grain sorghum processed products	EP	No		Yes[44/]	24 Months
- Wheat grain	TEP	Yes	00038908 00040086 00044426 00108203 00122715	No[39/]	
- Wheat milled products	EP	No		Yes[45/]	24 Months
Forage, Fodder, and Straw of Cereal Grains Group[46/]					
- Barley forage, hay, and straw	TEP	Yes	00038908 00040087 00044422 00108203	No[47/]	
- Corn forage, silage, and fodder	TEP	Yes	00023336 00023512 00037687 00038908 00040085 00048284 00108203	No[47/]	
- Oat forage, hay and straw	TEP	Yes	00038908 00040087 00044422 00108203	No[47/]	

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GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
- Rice straw	TEP	Yes	00038908 00040087 00044422	No[47/]	
- Sorghum forage, fodder, silage and hay	TEP	Partially	00038908 00040087 00044422 00108203 00109271	Yes[47/48/]	18 Months
- Wheat forage, hay, and straw	TEP	Yes	00038908 00040086 00044426 00108203 00122715	No[47/]	
Grass Forage, Fodder, and Hay Group	TEP	Yes	00076805 00108147	No[49/]	
Nongrass Animal Feeds (forage, fodder, straw and hay) Group	TEP	Yes	00076805 00108174	No[50/]	
- Alfalfa seed	EP	No		Yes[51/]	18 Months
Miscellaneous Commodities					
- Acerola[52/]					
- Asparagus	TEP	Partially	00108144	Yes[53/]	18 Months
- Avocados	TEP	Yes	00108149	No	
- Bananas (including plantains)	TEP	Yes	00108175	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
- Coconut[54/]					
- Coffee	TEP	Partially	00051980	Yes[55/]	18 Months
- Cotton	TEP	Yes	00060103 00108153 00061553 00108203 00108176	No	
- Cotton forage and hay[56/]					
- Figs[57/]					
- Guava	TEP	Yes	00059050	No	
- Kiwi Fruit[58/]					
- Mangos	TEP	No		Yes[59/]	18 Months
- Okra	TEP	No		No[60/]	
- Olives, processed	EP	Partially	00108175	Yes[61/]	24 Months
- Olive oil	EP	Partially	00108175	Yes[61/]	24 Months
- Palm Oils	EP	Yes	GS0178-028	No	
- Papayas	TEP	Yes	00063713	No	
- Peanuts	TEP	Partially	00028852	Yes[62/]	18 Months
- Peanut forage and hay	TEP	Partially	00028852	Yes[62/]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
- Peanut hulls	TEP	Partially	00028852	Yes[62/]	18 Months
- Peanut meal	EP	No		Yes[63/]	24 Months
- Peanut soapstock	EP	No		Yes[63/]	24 Months
- Peanut oil (crude and refined)	EP	No		Yes[63/]	24 Months
- Pineapple	TEP	No		No[64/]	
- Pineapple forage	TEP	No		Yes[65/]	18 Months
- Pistachio nuts	TEP	Yes	00111945	No	
- Sugarcane	TEP	Partially	00027235 00108140 00108168	Yes[66/]	18 Months
- Sugarcane forage	TEP	No		Yes[66/]	18 Months
- Sugarcane mollasses	EP	Yes	00027235 00108140 00108168	No[67/]	
- Tea	EP	Partially	00078823 00078824	Yes[68/]	24 Months
- Instant tea	EP	Partially	00078823 00078824	Yes[68/]	24 Months
- Watercress	TEP	No		No[69/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water	EP	Partially	00039381	Yes[70/71/]	18 Months
Magnitude of the Residue in Meat, Milk, Poultry, Eggs, Fish, and Shellfish					
- Cattle, Goats, Hogs, Horses, Poultry, and Sheep	TGAI or Plant Metabolites	Partially	00108115	No[72/]	
- Fish and Shellfish	EP	Partially	00036229 00076491	No[73/]	
Nature and Magnitude of the Residue in Drinking and Irrigation Water	EP	Yes	00039377 00077233 00039381 00077234 00077227 00077235 00077228 00077236 00077229 00077237 00077230 00077238 00077231 00077301 00077232 00108173	No[74/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.125 Residue Chemistry - Footnotes

1/ Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed for 3 days with N-phosphonomethyl ^{14}C glycine at a concentration in the total diet which will result in sufficient residues in the tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (milk and eggs must be collected twice daily.) The distribution, characterization, and quantification of residues must be determined in eggs, milk, muscle, fat, kidney, and liver. The samples from these studies must be analyzed by enforcement methods to ascertain that all metabolites of concern are adequately determined.

2/ The HLPC procedure that has undergone a successful method tryout, should be published in the PAM, Vol. II and a statement should be inserted in Method I (GLC) of the PAM, Vol II that discourages its use due to the lengthiness of the procedure.

3/ This crop group tolerance is not appropriate and should be deleted for the following reasons.

° Residue data are required for an additional commodity (radishes).

° The use pattern is much different for parsnips and rutabagas (wiper applications) and for turnips (spot treatment for site preparation) than for other root crops (preemergence or preplant). Should a new crop group tolerance be sought these group members should be deleted.

4/ The available data support the group tolerance of 0.2 part per million (ppm); however, individual tolerances should be established because the group in which the commodity is included is obsolete or the requirement for the appropriate current crop group should be satisfied.

5/ Residues must be determined in granules, chips, and dried potatoes processed from tubers bearing measurable residues. Exaggerated application rates may be necessary to achieve measurable residues. If residues are found to concentrate in any of these processed commodities, appropriate food addditive tolerances must be proposed.

6/ The requested data for parsnips will be upon their receipt, translated to rutabagas and based in these data, a separate tolerance should be established for rutabagas since the root crop vegetable group in which rutabagas was included is now obsolete.

7/ Residues of glyphosate and AMPA in or on parsnips harvested 14 days following two wiper applications made in opposite directions on the same day with 3 pound active ingredient/gallon (lb ai/gal) SC/L formulation using (in separate tests) roller and wick devices are required. One gal product in 10 gal solution must be applied by roller and one gallon product in 3 gal of solution must be applied by wick. Tests must be conducted in CA, IL, and PA or NY. These data will be translated to rutabagas.

§158.125 Residue Chemistry - Footnotes (cont'd)

8/ Residues must be determined in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable weathered residues. Exaggerated application rates may be necessary to achieve measurable residues. If residues are found to concentrate in any of these processed commodities, appropriate food/feed additive tolerances will be needed.

9/ Residues of glyphosate and its metabolites AMPA in or on turnips following two preplant treatments with the 0.96% RTU (0.72% ai) formulation sprayed directly on undesirable foliage to the point just before the spray begins to drip or run are required. A separate tolerance, based on the results of the requested data, be established for residues in or on turnips since the root crops vegetables group in which turnips was included is now obsolete.

10/ A crop group tolerance is not appropriate at the present time for the following reasons:

° Residue data are required for one additional group member (turnip tops); residue data for only one group member (sugar beet tops) are available.

° The use pattern is much different for turnips (spot treatment for site preparation) than for sugar beets, chicory, and garden beets (preemergence or preplant). Should a new crop tolerance be sought, turnips should be excluded.

11/ Based on data from other vegetables and root crops a separate tolerance of 0.2 ppm should be established for residues in or on this commodity since the leafy vegetables group in which the commodity was included is obsolete.

12/ Residues of glyphosate and its metabolite AMPA in or on turnip greens following two preplant treatments with 0.96% RTU (0.72% ai) formulation directed on underside foliage to the point just before the spray begins to drip or run off foliage are required.

13/ A crop group tolerance is not appropriate at the present time for the following reason:

° No residue data have been presented for any member of this group. In order to satisfy minimum data requirements, data should be submitted for onions (green and bulb) and either garlic, leeks, or shallots.

14/ Since the root crop vegetable group in which this commodity was included is obsolete and no data are available to support the established 0.2 ppm tolerance on onions a separate tolerance must be established. The following additional residue data are required:

° Combined residues of glyphosate and AMPA in or on onions (bulb and green) following preemergence applications with the 3 lb ai/gal SC/L formulation totaling 6 lb ai/A (the final application must be at 3.75 lb ai/A) in the states of CA and TX for spring onions and the states of CA and NY for dry bulb onions.

§158.125 Residue Chemistry - Footnotes (cont'd)

15/ A group tolerance is not appropriate at this time because no residue data have been submitted for celery and spinach. The following data are required if a crop group tolerance is desired:

° Data depicting combined residues of glyphosate and AMPA in or on celery following preemergence applications with 3 lb ai/gal SC/L formulation totaling 6 lb ai/A (with the final application at 3.75 lb ai/A). Separate tests must be conducted utilizing high and low volume equipment. Tests must be conducted in CA.

° Data depicting combined residues of glyphosates and AMPA in or on spinach following preemergence applications with the 3 lb ai/gal SC/L formulation totaling 6 lb ai/A (with the final application at 3.75 lb ai/A). Separate tests must be conducted utilizing both high and low volume ground equipment. Tests must be conducted in CA.

16/ The CFR will be amended by deletion of now obsolete leafy vegetable crop group and separate tolerances of 0.2 ppm should be established for glyphosate residues in or on lettuce, spinach, and celery.

17/ No data are available for celery, but based on the large amount of data available for various vegetable and root crops, we find the 0.2 ppm tolerances adequate.

18/ No data are available for spinach, but based on the large amount of data available for various vegetable and root crops we find the 0.2 ppm tolerance adequate.

19/ A crop group tolerance is not appropriate because no residue data have been presented for broccoli and mustard green, which are representative commodities of this group. The following data are needed if a crop group tolerance is desired:

° Combined residues of glyphosate and AMPA in or on mustard greens following preemergence applications with the 3 lb ai/gal SC/L formulation totaling 6 lb ai/A (the final application must be at 3.75 lb ai/A). Separate tests must be conducted utilizing both high and low volume ground equipment.

° A use on broccoli must be proposed and residue data reflecting the proposed use must be submitted.

20/ A separate tolerance of 0.2 ppm should be established since the tolerance was established as a member of the leafy vegetable group now obsolete. Alternatively, the appropriate crop group tolerance could be sought upon completion of the requirements.

21/ No data are available for cauliflower; however, based on the large amount of data available for various vegetable and root crops, we find the 0.2 ppm tolerance adequate.

§158.125 Residue Chemistry - Continued

22/ No data are available for kale; however, based on the large amount of data available for various vegetable and root crops, we find the 0.2 ppm tolerance adequate.

23/ No data are available for mustard greens; however, based on the large amount of data available for various vegetable and root crops, we find the 0.2 ppm tolerance adequate.

24/ A group tolerance of 0.2 ppm should be established for the combined residues of glyphosate and AMPA in or on legume vegetables except soybeans. Soybeans must be excluded from the crop group tolerance for the following reasons:

° The established 6 ppm for residues in or on soybeans differs from the 0.2 ppm tolerance for residues in or on other legumes by a factor greater than > 5.

° The use pattern for soybeans (postemergence and spot treatment) is much different than for other legumes (preemergence treatment only).

25/ A separate tolerance of 0.2 ppm should be established for legume vegetables except soybeans, since the seed and pod vegetable group in which these commodities were included is now obsolete.

26/ The following additional data are required to determine whether residues concentrate from processed soybeans to soapstock:

° Data depicting residues on soapstock processed from soybeans bearing measurable, weathered residues. If residues concentrate in soapstock, a feed additive tolerance must be proposed.

27/ A crop group tolerance should be established for the combined residues of glyphosate and AMPA in or on the foliage of legume vegetables, except soybean forage and hay. Soybean forage and hay must be excluded from the crop group tolerance for the following reasons:

° The established tolerances for residues in or on soybean forage and soybean hay (15 ppm) differ from the 0.2 ppm tolerance for residues in or on forage and hay of other legumes by a factor > 5.

° The use pattern for soybeans (postemergence spot and directed treatment) is much different than for other legumes (preemergence treatment only).

28/ A separate tolerance of 0.2 ppm be established for residues in or on the foliage of legume vegetables, except soybeans, since the seed and pod vegetables group in which these commodities were included is now obsolete.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.125 Residue Chemistry - Footnotes (cont'd)

29/ A crop group tolerance is not appropriate at the present time because residue data for members of the fruiting vegetables (except cucurbits) group are currently under review.

30/ A crop group tolerance is not appropriate at the present time because residue data for members of the cucurbit vegetable group are currently under review.

31/ Data are inadequate to support the citrus fruits group tolerance or a feed additive tolerance for dried citrus pulp. The following data are required on whole citrus fruit:

° Data depicting residues of glyphosate in or on whole grapefruit, lemons, and oranges harvested 14 days after the last of three applications of glyphosate at 3-4 month intervals (combined total application > 7.95 lb ai/A/yr) are required. Tests must be conducted in CA, FL, and TX. Alternatively you may clarify the calculation used to derive whole fruit residues from juice and peel fraction residues submitted under Pesticide Petition No. 6G1734.

° Data concerning residues from whole citrus fruit are required before concentration factors can be determined for processed citrus fractions (dried pulp, juice, molasses, oil).

32/ The data are insufficient to assess the 0.2 ppm tolerance for residues of glyphosate on stone fruits because data were not submitted on peaches, nectarines, or apricots harvested at the established 14-day PHI. The following additional data are required:

° Residues of concern in or on sweet or sour cherries, peaches, and plums or fresh prunes (representative commodities) harvested 14 days after the last of multiple applications with the 3 lb ai/gal SC/L (the final treatemnt at 3.75 lbs ai/A) totaling 7.95 lb ai/A. Tests on sour cherries must be conducted in MI; tests on sweet cherries must be conducted in MI; tests on plums or fresh prunes must be conducted in CA, OR, WA, and MI, and tests on peaches must be conducted in CA, SC, or GA, NJ,or PA. Applications are to be made using any appropriate method specified for these states in the label directions.

33/ Insufficient data were submitted to evaluate the concentration of residues in prunes processed from plums. The following additional data are required:

° Processing data from prunes derived from plums bearing measurable, weathered residues. If residues are found to concentrate in dried prunes, then an appropriate food additive tolerance must be proposed.

§158.125 Residue Chemistry - Footnotes (cont'd)

34/ Establishment of a crop group tolerance for small fruits and berries is not appropriate at the present time for the following reasons:

a. Data in support of a proposed tolerance for combined residues of glyphosate and the metabolite AMPA in or on small fruits (blueberries, blackberries, raspberries, and strawberries) are currently under review.

b. Additional data are required to support the established tolerance for residues in or on cranberries.

35/ No tolerance has been established for this commodity. A tolerance of 0.2 ppm has been proposed for crop group small fruits. These data are still under review and the adequacy of the proposed tolerance will not be addressed.

36/ The following additional data are needed to fully assess the established tolerance on cranberries:

° Residue data from tests in MA and WI reflecting wiper application at the maximum allowable concentration of 0.6 lb ai/gal solution, samples must be collected 30 days after application. These tests must be conducted in heavily weed-infested bogs, with the equipment operated at a slow ground speed and with the initial application in one direction followed by a second application in the opposite direction. Residue data from MA should reflect both flood- and dry-harvest cranberries.

37/ The following additional data are needed to determine whether food/feed additive tolerances are required for processed products of grapes:

° Data depicting residues in or on wet and dry pomace, raisin waste, and juice processed from grapes bearing measurable weathered residues. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration occurs, appropriate food/feed additive tolerances must be proposed.

38/ The established crop group tolerance for glyphosate residues in or on grain crops is not appropriate and should be deleted for the following reasons:

° The use pattern for rice (preemergence) is much different than for other grain crops (preemergence and post-emergence).

° State labels [24(c) registrations] permit postemergence wiper applications on sorghum grown in KS, MO, NE, NM, OK and TX and section 18 wheat grown in ID, OK, OR, and WA; the available data show that this application method may result in residues in or on sorghum and wheat grain in excess of the established 0.1 ppm tolerance.

° A tolerance increase for residues in or on wheat grain (but no other commodities in this group) has been proposed and these data are currently under review.

§158.125 Residue Chemistry - Continued

39/ A separate tolerance of 0.1 ppm must be established for residues on this commodity because a group tolerance for grain crops is not appropriate at the present time.

40/ No additional data are needed because similar data requirements exist for wheat-milled products which, upon their receipt, will be translated to barley milled products.

41/ The following additional data are needed to determine whether concentration of residues occurs in the processed products of field corn grain:

° Field corn grain bearing detectable weathered residues of glyphosate must be processed into oil (crude and refined) and milled products; residues of glyphosate per se and AMPA in these products must be sought. exaggerated rates may be necessary to obtain detectable residues in or on grain. If residues concentrate in any of these processed products, appropriate food additive tolerances must be proposed.

42/ Additional data are not required for this topic because similar data requirements exist for wheat milled products which, upon their receipt, will be translated to oat milled products.

43/ Wiper application data reflecting the 14-day PHI should be submitted and an appropriate tolerance for glyhphosate residues in or on sorghum grain following postemergence treatments using wiper devices must be proposed. Otherwise, the following active existing 24(c) registrations must be cancelled KS 820001, MO 820014, NE 820009, NM 820001, OK 820010, and TX 820023 must be canceled.

44/ The following additional data are required to determine whether concentration of residues occurs in processed products of grain sorghum:

° Sorghum grain bearing detectable weathered residues of glyphosate must be processed into flour and milled products; residues of glyphosate per se and AMPA in these products must be sought. Exaggerated rates may be necessary to obtain detectable residues in or on grain. If residues concentrate in any of these processed products, appropriate food additive tolerances must be proposed.

45/ The following additional data are required to determine whether concentration of residues occur in processed products of wheat grain:

° Wheat grain bearing detectable weathered residues of glyphosate must be processed into milled products, and residues of glyphosate per se and AMPA in these products must be sought. Exaggerated rates may be necessary to obtain detectable residues in or on grain. If residues concentrate in any of these processed products, appropriate food additive tolerances must be proposed.

§158.125 Residue Chemistry - Footnotes (cont'd)

46/ A crop group tolerance is not appropriate at the present time for the following reasons:

- The use pattern for rice (preemergence) is much different than for other grain crops (preemergence and postemergence).
- State labels [24(c) registrations] permit postemergence wiper applications on sorghum in KS, MO, NE, NM, OK, and TX. The available data show that this application method may result in residues in or on sorghum forage in excess of the established 0.2 ppm tolerance (forage grasses group).

47/ Separate tolerances of 0.2 ppm should be established for residues in or on these commodities because a group tolerance for forage grasses is not appropriate at the present time.

48/ The existing 24(c) registrations (KS 820001, MO 820014, NE 820009, NM 8200001, OK 820010, and TX 820023) must be cancelled or you could submit data depicting residues 14 days after wiper applications at maximum registered rates and propose appropriate tolerances for glyphosate residues in or on sorghum forage, fodder, hay, and silage.

49/ Separate crop group tolerances of 100 ppm should be established for residues in or on grass forage and hay. All the established tolerances for residues in or on grasses, including "forage grasses" and "grasses, forage" should be deleted.

50/ The existing, conflicting tolerances on alfalfa, clover, and forage legumes should be deleted. Separate tolerances for residues of glyphosate and AMPA of 100 ppm should be established for residues of forage and hay of nongrass animal feeds.

51/ The following data are required to determine whether a food additive tolerance must be proposed for residues in or on alfalfa seed:

- Data depicting residues in or on alfalfa seed from alfalfa hay bearing measurable weathered residues. If the concentration of residues in seed is higher than in hay, an appropriate feed additive tolerance must be proposed.

52/ The data supporting this tolerance are currently under review, therefore a conclusion on the adequacy of this tolerance will not be made at this time.

53/ Residue data from green asparagus harvested 8-15 days following the last two preemergent broadcast applications are required. The first treatment must be made at 2.25 lb ai/A and the last at 3.75 lb ai/A to total 6 lb ai/A. Test sites should include the Sacramento/San Joaquin River delta of CA, MI, and MD or NJ.

§158.125 Residue Chemistry - Footnotes (cont'd)

54/ The available data supporting the proposed tolerance for glyphosate residues in or on coconut are currently under review, therefore, a conclusion regarding the adequacy of the proposed tolerance will not be made at this time.

55/ Residue data must be submitted of concern in or on coffee beans harvested at 14 days after the last of multiple directed spray applications with the 3 lb ai/gal SC/L totaling 7.95 lb ai/A. Tests must be conducted in HI, Brazil, Columbia, El Salvador, and Mexico.

56/ The established tolerances for residues in or on cotton forage and hay are inappropriate and should be cancelled since hay is not considered to be a raw agricultural commodity of cotton and feeding and grazing restrictions exist.

57/ The available data in support of the proposed tolerance for glyphosate residues in or on figs are currently under review, therefore, a conclusion regarding the adequacy of the proposed tolerance will not be made at this time.

58/ The available data in support of the proposed tolerance for glyphosate residues in or on kiwi fruit are currently under review; therefore, a conclusion regarding the adequacy of the proposed tolerance will not be made at this time.

59/ No residue data for glyphosate in or on mangos were submitted to support the established tolerance. The following data are required:

- Data depicting residues in or on mangos harvested 14 days after the last of two directed-spray applications at 3.75 lb ai/A. Test must be conducted in FL.

60/ No data are available concerning residues in okra. However, based on the large amount of data available for various vegetables and root crops, we find a 0.2 ppm tolerance adequate.

61/ The following additional documentation and data are required:

- Documentation that the approved labels (use directions) from Greece, Italy and Spain reflect the data submitted in PP#9F2223/FAP#0H5255 (a maximum, single application rate of 3.8 lb ai/A or multiple applications at lesser rates but with the total of all annual applications not to exceed 3.8 lb ai/A). The labeled preharvest interval should not be less than 21 days. If the labels do not reflect these data, you may revise the labels or submit additional residue data to adequately support the amount labeled. If the latter, we recommend data be generated from processed olives from Spain and processed olive oil from Italy and Spain.

- Documentation of the olive-curing process described as "The standard commercialization procedure for table olives" in PP#9F2223/FAP#0H5255.

§158.125 Residue Chemistry - Footnotes (cont'd)

62/ The following additional data are required on peanut nutmeats, forage, hay, and hulls to assess the appropropriateness of the established tolerances:

° Data depicting residues in or on nutmeats, forage, hay, and hulls sampled 60 days after a spot treatment at 6 lb ai/A (0.15 lb ai/gal solution). Samples must be collected in and at the edge of treated areas. Tests must be conducted in VA, GA, and TX.

63/ The following processing data are required:

° Data depicting residues in or on meal, soapstock, and crude and refined oil processed from nutmeats bearing measurable weathered residues. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

64/ No data were submitted to support the request for a tolerance for glyphosate residues in or on pineapple. Based on the built-in 21-month PHI (interval from intercycle, fallow period to harvest of mature fruit), we defer the requirement for residue data for fruit.

65/ Since forage of pineapple is considered a food item, the following are required:

° A feeding and grazing restriction for pineapple forage. Alternatively, you may submit tests from HI reflecting residues in or on forage harvested 8 weeks after the last of two preplant broadcast applications at 2.25 and 3.75 lb ai/A, respectively, and propose an appropriate tolerance.

66/ The following additional data are required on sugarcane and sugarcane forage:

° Data depicting residues in or on cane harvested on the day of a postemergence. Directed spray application must be applied at 6-15 lb ai/100 gal (7.95 lb ai/A) and in or on forage harvested 8 weeks after treatment. Tests must be conducted in LA and FL. A tolerance must be proposed for residues in or on forage and an appropriate tolerance revision must be proposed for residues in or on cane. Alternatively, a grazing restriction may be proposed and no forage data submitted.

67/ The established tolerance on molasses appears adequate at present, but will be reevaluated on receipt of data requested for cane.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.125 Residue Chemistry - Footnotes (cont'd)

68/ The following additional data are required to fully assess the adequacy of food additive tolerances for imported dried tea:

° Reaffirmation of foreign distribution of glyphosate for use on tea plantations.

° Documentation of label directions from all countries in which glyphosate is registered for this use.

We recommend that a 7 ppm food additive tolerance revision for instant tea be made to sufficiently cover the 5-7X processing concentration factor.

69/ No data are available to support the established tolerance for residues in or on watercress. Based on the large amount of data available for vegetable and root crop vegetables a 0.2 ppm tolerance is adequate for watercress.

70/ The following data are required:

° Data must be submitted reflecting sprinkler irrigation of crops with natural waters which have been treated with gyphosate to control severe aquatic weed infestations. The protocol should include irrigation of several foliar crops such as corn (forage), alfalfa, grasses, and a leafy vegetable treated with water from large impounded bodies of water and rivers.

71/ The tolerances established for the currently obsolete crop groupings should be deleted and tolerances for residues in or on all crop groups in the currently accepted crop grouping scheme and all major irrigated crops not included in a crop group (cotton, sugarcane, peanuts, etc.) be established at a level consistent with data resulting from the protocol requested.

72/ Presently, the nature and storage stability of residues in ruminants (including milk) and poultry (including eggs) are not adequately understood. Additional residue data are required for raw agricultural commodities and processed commodities. Once the requested data are received, the adequacy of the available data and established tolerances will be assessed.

73/ Insufficient data are available to ascertain the nature of residues in natural waters. Therefore, we will defer an opinion as to the adequacy of available data and established tolerances until the requested data are received. The proposed tolerance on shellfish will not be evaluated because the data supporting this tolerance are currently under review.

74/ If aquatic metabolism data requested by Exposure Assessment Branch indicate the presence of additional degradates of toxicological concern in natural waters following treatment with glyphosate, additional residue data depicting the levels of such degradates in natural water following registered use will be required. A restriction prohibiting use of treated pond water for irrigation purposes within 24 hours of treatment must be placed on the label.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D, F,G,H	Yes	00108192	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,C,D,G	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A,F	No		Yes	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F,G,H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[1/]	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,D	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C,D	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D	Partially	00108192	Yes	12 Months
163-2 - Volatility (Lab)	TEP	A,F	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A,F	No		Yes[2/]	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	C,D	No		Yes	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-4 - Combination and Tank Mixes						---
164-5 - Soil, Long-Term	TEP	A,C	No		Yes[3/]	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (confined)	PAIRA	A,C	No		Yes	39 Months
165-2 - Rotational Crops (field)	TEP	A,C	No		Yes	50 Months
165-3 - Irrigated Crops	TEP	C,D	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B,C, D,G	No		Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	A,B,C D,G	No		Yes	12 Months
Subpart K Re-entry	TEP[4/]					

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.130 Environmental Fate - Footnotes

1/ Not required if an acceptable anaerobic aquatic metabolism study is conducted.

2/ Deferred pending receipt of acceptable laboratory volatility data.

3/ Requirement is contingent upon results of studies in 162-1 and/or studies in 164-1 and 164-2.

4/ No data required because of low toxicity and exposure from present use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,C,D, F,G,H	Yes	00067039	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,C,D, F,G,H	Yes	00067039	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,C,D, F,G,H	No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,C,D, F,G,H	No		No[1/]	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent	TGAI	A,B,C,D, F,G,H	No		No[2/]	
- Non-rodent (dog)		A,B,C,D, F,G,H	No		No[2/]	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,C,D, F,G,H,	Yes	00098460	No	
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,C,D, F,G,H	No		No[3/]	
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,C,D, F,G,H	No		No[4/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology - Continued						
82-5 - 90-Day Neurotoxicity:	TGAI	A,B,C,D,	No		No[5/]	
- Hen		F,G,H				
- Mammal		A,B,C,D, F,G,H	No		No[5/]	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species	TGAI					
- Rodent		A,C,D, F,H	Yes	00093879	No	
- Non-rodent (dog)		A,C,D, F,H	Partially	00153374	Yes[6/]	50 Months
83-2 - Oncogenicity - 2 species	TGAI					
- Rat (preferred)		A,C,D, F,H	Partially	00093879	Yes[7/]	50 Months
- Mouse (preferred)		A,C,D, F,H	Partially	00130406	Yes[8/]	50 Months
83-3 - Teratogenicity - 2 Species	TGAI					
- Rat		A,B,C,D, F,G,H	Yes	00046362	No	
- Rabbit		A,B,C,D, F,G,H	Yes	00046363	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology - Continued						
83-4 - Reproduction - Rat 2-generation	TGAI	A,C,D,H	Yes	00081674 00105995	No	
MUTAGENICITY TESTING:						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,C,D F,G,H	Yes	00078620 00132683	No	
84-2 - Structural Chromosomal Aberration	TGAI	A,B,C,D, F,G,H	Yes	00046364 00132681 00132685	No	
84-4 - Other Genotoxic Effects	TGAI	A,B,C,D, F,G,H	Yes	00078619 00132686	No	
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA	A,C,D F,G,H	No		Yes	24 Months
85-2 - Dermal Penetration	Choice	N/A[9/]			No	
86-1 - Domestic Animal Safety	Choice	H	No		No[10/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.135 Toxicology - Footnotes

1/ Glyphosate is not an organophosphate insecticide or carbamate; therefore, this test is not required.

2/ These studies are not required because the one year dog and chronic rat study will fulfill these requirements.

3/ This study is not required because the use pattern does not indicate a potential for purposeful dermal application or prolonged contact.

4/ This study is not required because the use pattern does not indicate a potential for repeated inhalation exposure at concentrations likely to be toxic.

5/ These studies are not required because glyphosate is not an organophosate insecticide or carbamate and there is no evidence of neurotoxicity or neuropathy in any of the submitted studies.

6/ Additional data is required to address findings in this study.

7/ A repeat rat study is required in which the highest dose tested is a maximally tolerated dose (MTD).

8/ A repeat mouse study is required. A protocol should be submitted prior to initiation of a new study.

9/ N/A = Not applicable for the purpose of this standard.

10/ It is unlikely that a hazard to domestic animals exist as a result of this use; therefore the test is not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	N/A[1/]			No	
132-1 - Soil Dissipation	TEP	N/A			No	
133-3 - Dermal Exposure	TEP	N/A			No	
133-4 - Inhalation Exposure	TEP	N/A			No	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	N/A			No	
201-1 - Drift Field Evaluation	TEP	N/A			No	
Special Tests						

1/ N/A = not applicable for the purposes of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C,D F,G,H	Yes[1/]	00108204	No	
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland game bird		A,B,C,D, F,G,H	Yes[1/2/]	00108107	No	
- Waterfowl		A,B,C,D, F,G,H	Yes	00076492	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,C,D F,G,H	No	00076492	No[3/]	
71-4 - Avian Reproduction	TGAI					
- Upland game bird		A,B,C, D,G	Yes[4/]	00108207	No	
- Waterfowl		A,B,C, D,G	Yes	00036328 00111953	No	
71-5 - Simulated Field Testing	TEP					
- Mammals		A,B,C, D,G	No		No[5/]	
- Birds		A,B,C, D,G	No		No[5/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
- Actual Field Testing	TEP					
- Mammals		A,B,C, D,G	No		No[5/]	
- Birds		A,B,C, D,G	No		No[5/]	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater fish species	TGAI	A,B,C,D F,G,H	Yes[1/2/]	00136339 GS0178-025	No	
- Warmwater fish species		A,B,C,D, F,G,H	Yes	00108112 00108205	No	
	TEP[4/]	A,B,C, D,G	Yes[6/]	00070895 00078661 00070897 00078662 00078655 00078664 00078656 00078665 00078658 00108205 00078659 00124760 GS0178-025	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C,D, F,G,H	Yes	00108172	No	
	TEP[4/]	A,B,C, D,G	Yes[6/]	00070893 00078666 00078657 00124762 00078660 GS0178-025 00078663	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,B,C,D	No[7]		No[8]	
- Mollusk	TGAI	A,B,C,D	Partially[7]	00108110	No[9]	
- Shrimp	TGAI	A,B,C,D	Yes[7]	00108111	No	
72-4 - Fish Early Life Stage	TGAI	N/A[10]	No		No	
- Aquatic Invertebrate Life Cycle		A,B,C,D G,H	Yes	00124763	No	
72-5 - Fish Life Cycle	TGAI	A,B,C,D, G,H	Yes	00108171	No	
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product					
- Crustacean		N/A[10]	No		No	
- Fish		N/A[10]	No		No	
- Insect Nymph		N/A[10]	No		No	
- Mollusk		N/A[10]	No		No	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlire and Aquatic Organisms - Continued						
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	N/A	No		No[11/]	
- Actual Field Testing - Aquatic Organism		N/A	No		No[11/]	

1/ Required to support manufacturing use product for reformulation into end use.

2/ Only one species required.

3/ These data are required if available acute toxicology data indicate an acute hazard. Available data do not trigger this requirement.

4/ Label directions allow for repeat applications.

5/ These data are required if available acute data on birds and mammals indicate an acute hazard. Available data do not trigger these requirements.

6/ These tests are required when inerts are likely to be toxic.

7/ These studies are required because of the potential exposure of estuarine species, for application on cotton, sugarcane, corn, soybeans, ditchbanks and tide areas, and potential hazard to endangered mussels.

8/ Existing glyphosate data for freshwater and estuarine crustacean plus numerous freshwater fish studies suggest little toxicity to estuarine fish.

9/ The glyphosate TL50 > 10 mg/L is 2.7 times greater than the amount expected after direct application to a 6-inch-acre layer of water. Therefore, further testing is not warranted.

10/ N/A = not applicable for purposes of this standard.

11/ These studies are required if available acute toxicity data on aquatic organisms indicate an acute hazard. Available data do not trigger these requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	B,D,G	No		No[1/]	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Yes[2/]	9 Months
122-1 - Vegetative Vigor	TGAI	B,D,G	No		Yes[2/]	9 Months
122-2 - Aquatic Plant Growth	TGAI	B,D,G	No		Yes[2/]	9 Months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Reserved[3/]	
123-1 - Vegetative Vigor	TGAI	B,D,G	No		Reserved[3/]	
123-2 - Aquatic Plant Growth	TGAI	B,D,G	No		Reserved[3/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
TIER III						
124-1 - Terrestrial Field	TEP	B,G	No		Reserved[4/]	
124-2 - Aquatic Field	TEP	D	No		Reserved[4/]	

1/ Data are required only for Special Review and certain public health situations.

2/ These studies are required because there is evidence of phytotoxicity problems from application of this pesticide and open literature data are not available on these tests and because the use of this product may pose hazards to endangered or threatened species.

3/ These studies are reserved pending results of Tier I testing.

4/ These studies are reserved pending results of Tier II testing if required.

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honeybee acute contact toxicity	TGAI	A,B, G,H	Yes	00026489	No	
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B, G,H	No		No[1/]	
141-4 - Honeybee subacute feeding study	(Reserved)[2/]					
141-5 - Field testing for pollinators	TEP	A,B, G,H	No		No[1/]	
NONTARGET INSECT TESTING AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)[3/]					
142-2 - Aquatic insect life-cycle study	(Reserved)[3/]					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)[3/]					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[3/]					

TABLE A
GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

§158.155 Nontarget Insect - Footnotes

1/ As data from the acute study indicate very low toxicity, no further testing is required.

2/ Reserved pending development of test methodology.

3/ Reserved pending Agency decision as to whether this data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP		No	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Disclosure of Manufacturing Process	MP		No	N/A	Yes[2/3/]	6 Months
61-3 - Discussion of Formation of Impurities	MP		No	N/A	Yes[4/]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP		No	N/A	Yes[5/]	12 Months
62-2 - Certification of Limits	MP		No	N/A	Yes[6/]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP		No	N/A	Yes[7/]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP		No	N/A	Yes	6 Months
63-3 - Physical State	MP		No	N/A	Yes	6 Months
63-4 - Odor	MP		No	N/A	Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry - Continued						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP		No	N/A	Yes	6 Months
63-12 - pH	MP		No	N/A	Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP		No	N/A	Yes	6 Months
63-15 - Flammability	MP		No	N/A	Yes	6 Months
63-16 - Explodability	MP		No	N/A	Yes	6 Months
63-17 - Storage Stability	MP		No	N/A	Yes	15 Month
63-18 - Viscosity	MP		No	N/A	Yes	6 Months
63-19 - Miscibility	MP		No	N/A	Yes	6 Months
63-20 - Corrosion Characteristics	MP		No	N/A	Yes	15 Months
Other Requirements						
64-1 - Submittal of samples	MP		No	N/A	Yes	6 Months

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING GLYPHOSATE

§158.120 Product Chemistry - Footnotes (cont'd)

2/ Details of manufacturing process, including the relative amounts of beginning materials, a description of equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures for 41.09% ai formulation intermediate (FI), the 53.5% ai FI, the 62% ai FI, the unregistered technical isopropylamine salt glyphosate used to produce the FI's, and the unregistered technical trisodium salt are required.

3/ The names and addresses of manufacturers, producers, or suppliers of each beginning material used to manufacture the 41.04% ai FI, the 53% ai FI, the unregistered technical products to produce the FIs and the unregistered trisodium salt are required. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties must be submitted.

4/ A discussion is required of each impurity believed to be present at 0.1% or greater, based on knowledge of beginning materials, all possible chemical reactions and any contamination.

5/ Five or more representative samples of 41.04% ai FI, the 53.5% ai FI, the 62% ai FI, and the unregistered technical trisodium salt analyzed for the amount of active ingredient and each impurity present at 0.1% (w/w) (including any nitroso-amines which may be present at ~0.1 ppm) are required.

6/ The following additional data are required:

- Upper and lower limits must be provided and certified for each intentionally added inert in the FI's. Also, the purpose of each intentionally added inert in EPA Registration Nos. 524-318 and 524-333 must be specified.

- Upper and lower limits must be provided and certified (FI's only) for each impurity present at 0.1% (w/w) or greate in the FI's, the unregistered isopropylamine salt technical(s) from which the FI's are produced, and the technical trisodium salt.

- Upper and lower limits must be provided and certified (FI's only) for glyphosate in the FI's, the unregistered technical products from which the FI's are produced, and in the technical trisodium salt.

- All nitrosoamines must be identified and quantified in six samples each of the registered FI's, the unregistered technical trisodium salt, and the unregistered technicals from which the FI's are produced; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm on N-nitroso contaminants must be used. An upper limit must be presented and certified (FI's only) for all nitrosoamines found.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING GLYPHOSATE

§158.120 Product Chemistry - Footnotes (cont'd)

7/ The following additional data are required:

° Quantitative methods to determine glyphosate and all impurities and intentionally-added inerts for which a certified limit is required in the 40.04% ai FI, the 53.3% ai FI, and the 62% ai FI. Analytical methods for glyphosate and impurities at > 0.1% (w/w) are also required for the unregistered technical glyphosate product(s) used to produce the FI's and the unregistered technical trisodium salt. Each method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE
PRODUCTS CONTAINING GLYPHOSATE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,C,D, F,G,H	Yes	00067039	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,C,D, F,G,H	Yes	00067039	No	
81-2 - Acute Inhalation Toxicity - Rat	MP	A,B,C,D, F,G,H	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,C,D, F,G,H	Yes	00067039	No	
81-4 - Primary Dermal Irritation - Rabbit	MP	A,B,C,D, F,G,H	Yes	00067039	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,C,D, F,G,H	No		Yes	9 Months

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemicals Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section III indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #)

[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)]	RCRA #	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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III. USE INDEX APPENDIX

GLYPHOSATE, ISOPROPYLAMINE SALT*

TYPE PESTICIDE: Herbicide

FORMULATIONS:
FI (3 lb/gal, 4 lb/gal, 62%)
EC (1.04 lb/gal)
SC/L (0.42 lb/gal, 3 lb/gal, 4 lb/gal, 5%, 6.6%)
RTU (0.5%, 0.96%, 1%)
PrL (0.75%)

GENERAL WARNINGS AND LIMITATIONS: Glyphosate is a broad spectrum post-emergence systemic herbicide that can be used for the control of most annual weeds, a large number of herbaceous and woody perennials, and grasses. Because of the non-selective nature of this herbicide, it may be applied either as a broadcast spray before planting or before emergence of the crop, or as a directed application in established crops, or to control weeds that are taller than the crop using recirculating or wiper applicators, or as a broadcast spray to achieve total vegetation kill for turf renovation or site preparation. It may also be used for weed control in non-crop areas and for spot treatment in crops. Apply with a nonionic surfactant. Do not allow spray, drift, or mist to come in contact with green foliage, green stems, or fruit of crops, desirable plants, or trees. Spray contact with any part other than mature bark on the main trunk of trees can result in serious damage to the plant. For best results, weeds should be actively growing and not under stress of drought or disease at the time of application. Control of perennials increases with plant maturity at the time of application. If weeds or brush have been mowed, or trees have been cut, allow regrowth to reach the recommended stage prior to application. Rainfall or irrigation occuring within 6 hours may reduce effectiveness; heavy rainfall or irrigation within 2 hours after application may require retreatment. Use the higher dosages and gallonages for control of dense vegetation unless otherwise specified. Do not disturb treated vegetation for a few days, and delay tillage for up to 7 days after application.

Thoroughly spray weed foliage, but not to the point of run-off. Repeat treatments may be necessary to control late germinating weeds or weeds regenerating from underground rhizomes.

Glyphosate does not provide residual control; plants that emerge after treatment will not be controlled. Dosages have been calculated using the acid equivalent of glyphosate. Tolerances have been given for combined residues of glyphosate (N-(phosphonomethyl)glycine) and its metabolite aminomethylphosphonic acid.

*Roundup
N-(phosphonomethyl)glycine, isopropylamine salt

GLYPHOSATE, ISOPROPYLAMINE SALT

METHODS OF APPLICATION (continued)

Wiper Applicators (Roller or Wick) - For roller applications, mix 3 lbs a.e. in 9 or 19 gallons of water. Maintain roller speed at 40 to 60 RPM. For wick applicators mix 3 lbs a.e. in 2 gallons of water. In severe infestations, reduce ground speed to ensure proper weed contact. Best results may be obtained if 2 applications are made in opposite directions.

Hand-Held Wipers - These are small-scale wiper applicators used for spot treatments.

TIME REQUIRED FOR CONTROL: Visible effects occur in 2 to 4 days on annual weeds and in 7 to 10 days on perennials.

PHYTOTOXICITY TO TARGET WEEDS: A gradual wilting and yellowing, leading to browning and necrosis.

PHYTOTOXICITY TO CROPS: Same as for the weeds.

MODE OF ACTION: The proposed mechanism of action is in the inhibition of the aromatic amino acid biosynthesis pathway leading to reduced protein synthesis and inhibited growth.

BROADLEAF WEEDS CONTROLLED:

BIBE	Alfalfa	
AAAB	Annual broadleaf weeds	
AAAE	Annual weeds	
AKAA	Aster	
AAAG	Biennial weeds	
AFBJ	Bigroot morninglory	(9)(24)
ACAA	Bindweed	
BIBB	Black medic	
ADDH	Blackseed plantain	
AKBA	Blue mustard	
BAAA	Brassbuttons	
ABBD	Broadleaf plantain	
AAAC	Broadleaf weeds	
ABBC	Buckhorn plantain	
AWBG	Bull thistle	
BIAA	Burclover	
AGAA	Buttercup	
AWBB	Canada thistle	(3)(5)(14)
CAAA	Catsear	
AAAC	Chickweed	
AVBA	Chicory	
AAAB	Clover	
ABBB	Coast fiddleneck	
DQAA	Cocklebur	(7)
AOBB	Common chickweed	
CXBK	Common groundsel	

GLYPHOSATE, ISOPROPYLAMINE SALT

BROADLEAF WEEDS CONTROLLED (continued)

›ZAAAHH	Little bittercress	
›AZAOBA	Little starwort	
›BKBDBB	London rocket	
›DAAHAA	Mallow	
›BFAHBB	Mayweed	
›AMAAAB	Milkweed	(3)(5)(6)
›EFADBA	Moneywort	
›BGAAAB	Morningglory	
›AZADBC	Mouseear chickweed	
›BFAQBC	Musk thistle	(3)(5)
›BKAAAC	Mustard	
›EWAIAA	Nightshade	
›AAAACV	Nimblewill	
›EMAHAA	Oldenlandia	
›EUAIBA	Oldfield toadflax	
›EAAGBO	Pennsylvania smartweed	
›FFARAA	Pennywort	
›BKAWAA	Pepperweed	
›AAAAAD	Perennial broadleaf weeds	
›AAAAAF	Perennial weeds	
AAAABI	Pigweed	
DXABAA	Plantain	
BFCEBF	Prickly lettuce	
EFAEAA	Primrose	
EAAGBD	Prostrate knotweed	
AFACBC	Prostrate pigweed	
BVAGBQ	Prostrate spurge	
FMAFBB	Puncturevine	
BFBPBF	Purple cudweed	
AAAABP	Purslane	
BFAEAA	Ragweed	
CQBYBH	Red clover	
COAFBC	Red deadnettle	
EAAHBB	Red sorrel	
AFACBI	Redroot pigweed	(3)(5)(7)
BDAKBA	Russian thistle	
BKAHBA	Shepherdspurse	
EWAIBD	Silverleaf nightshade	(3)(5)(16)
BKAGBB	Smallseed falseflax	
EAAGAD	Smartweed	
BFCABA	Smooth catsear	
AFACBE	Smooth pigweed	
EAAHAB	Sour dock	
BFDCAA	Sowthistle	
BFAOBA	Spanishneedles	(1)(4)(9)
BVAGBK	Spotted spurge	
BVAGAA	Spurge	
ZAAAGJ	Spurweed	
FGAEBA	Stinging nettle	
BFBUAA	Sunflower	(3)(5)(7)
EAAGBG	Swamp smartweed	

BROADLEAF WEEDS CONTROLLED (continued)

(18) Apply 3 lb a.e./A when most weeds have reached the late bud to flower stage. Apply in late summer or fall for best results. Allow 7 or more days after application before tillage.

(20) Apply 3 to 3.75 lb a.e./100 gal using hand-held equipment only. Apply when weeds are at or beyond the bloom stage. Use higher dosage for weeds that have reached the woody stage. Allow 7 or more days after application before tillage.

(21) Apply 2.25 lb a.e./A when most weeds have reached the late bud to flower stage. Allow 7 or more days after application before tillage.

(24) Apply 6 lb a.e./100 gal using hand-held equipment to weeds that are at or beyond the bloom stage. Repeat applications will be required. Allow 7 or more days after application before tillage.

(30) Apply 3 lb a.e./A as a broadcast spray, or 6 lb a.e./100 gal using hand-held equipment for control. Repeat applications will be necessary to maintain control.

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCABMBE	Alta fescue	
PCACKBA	Annual bluegrass	
PCAAAAB	Annual grasses	
PCACFBM	Bahiagrass	
PCABSAA	Barley (volunteer)	
PCABHBB	Barnyardgrass	
PCAADAA	Bentgrass	
PCAAZBA	Bermudagrass	(3)(5)(11)
PCAAAAN	Biennial grasses	
PCACKAA	Bluegrass	
PCAATAA	Brome	
PCACFBN	Brownseed paspalum	
PCACKBB	Bulbous bluegrass	
PCADHBA	Centipedegrass	
PCACTBA	Common rye	(2)(4)
PCADPBA	Corn (volunteer)	(2)(4)(8)
PCABFAA	Crabgrass	
PCAADBC	Creeping bentgrass	
PCACFBC	Dallisgrass	
PCAATBM	Downy brome	
PCABMAA	Fescue	
PCAAWBB	Field sandbur	
PCACUAA	Foxtail	
PCADEBA	Giant cutgrass	
PCABIBA	Goosegrass	
PCABUBF	Green foxtail	

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

(9) Apply 1.5 lb a.e./A for control.

(10) Partial control only.

(11) Apply 2.25 to 3.75 lb a.e./A. Use the lower dosage for partial control and the higher dosage for control. Apply when seedheads are present. Retreatment may be necessary for control. Allow 7 or more days after application before tillage.

(13) Apply 1.5 to 2.25 lb a.e./A when most grasses have reached the boot to head stage. Allow 7 or more days after application before tillage.

(17) Apply 2.25 lb a.e./A, or 3 lb a.e./100 gal using hand-held equipment when most weeds have reached the 7-leaf stage. Allow 7 or more days after application before tillage.

(19) In annual cropping systems apply 0.75 to 1.5 lb a.e./A, using 0.75 lb a.e. plus surfactant in 5 to 10 gallons of water per acre; or 1.5 lb a.e in 10 to 40 gallons of water per acre. In noncrop areas or in areas where annual tillage is not performed, apply 1.5 to 2.25 lb a.e. in 10 to 40 gallons of water per acre. For best results, apply when most weeds are at least 18 inches in height and have reached the boot to head stage of growth. Allow 7 or more days after application before tillage. Do not tank mix with residual herbicides when applying 0.75 lb a.e./A rate.

(22) Apply 2.25 lb a.e./A as a broadcast spray, or 3 lb a.e./100 gal using hand-held equipment to control existing weeds and immature nutlets attached to treated weeds. Apply when weeds are in flower or when new nutlets can be found at rhizome tips. Nutlets which have not germinated will not be controlled. Repeat. Tillage will stimulate nutlet germination.

(23) In annual cropping systems apply 0.75 to 1.5 lb a.e./A, using 0.75 lb a.e. plus a surfactant in 5 to 10 gallons of water per acre; or 1.5 lb a.e. in 10 to 40 gallons of water per acre. In pastures, areas coming out of sod, areas which are not tilled, or areas where annual crops are not grown, apply 1.5 to 2.25 lb a.e. in 10 to 40 gallons of water per acre. Make applications when weeds are 8 to 12 inches in height (3- to 4-leaf stage). Do not till between harvest and fall applications or in the fall or spring prior to spring applications. Allow 3 or more days after application before tillage. Do not tank mix with residual herbicides when applying 0.75 lb a.e./A.

(25) Apply 3 to 3.75 lb a.e./A to provide partial control when most weeds are at or beyond the seedhead stage. To maintain control, repeat applications will be required. Make fall applications before a frost. Allow 7 or more days after application before tillage.

WOODY PLANTS CONTROLLED (continued)

AQACBA	Trumpetcreeper	(28)
CZABBA	Tuliptree	(10)
ACABBB	Vine maple	(10)
FKADBA	Virginia creeper	
BWAFBB	White oak	(10)
EOACAA	Willow	(35)
AHABBB	Winged sumac	(10)

(10) Partial control only.

(27) Apply 2.25 to 3 lb a.e./A as a broadcast spray, or 3 to 4.5 lb a.e./100 gal using hand-held equipment for weed control.

(28) Apply 1.5 to 2.25 lb a.e./A as a broadcast spray, or 3 to 4.5 lb a.e./100 gal using hand-held equipment for weed control.

(29) Apply 1.5 lb a.e./A as a broadcast spray, or 3 lb a.e./100 gal using hand-held equipment for weed control.

(32) Apply 3 to 3.75 lb a.e./A as a broadcast spray, or 6 lb a.e./100 gal using hand-held equipment. Repeat applications may be necessary to maintain control. Make fall applications before leaves lose green color.

(33) Apply 3 to 4.5 lb a.e./100 gal using hand-held equipment for weed control when at least 50 percent of the new leaves are fully developed.

(34) Apply 1.5 to 3 lb a.e./A as a broadcast spray for partial control when weeds are at or beyond full flowering.

(35) Apply 2.25 lb a.e./A as a broadcast spray, or 3 lb a.e./100 gal using hand-held equipment for weed control.

(40) Apply 1 ml/2 to 3 inch DBH by frill or injection treatment for control.

(41) Apply 1 ml/2 to 3 inch DBH by frill or injection treatment for suppression.

AQUATIC WEEDS CONTROLLED:

AFABBA	Alligatorweed	(36)
FDABAA	Cattail	(37)
IGABAA	Chara	
CACJAA	Phragmites	(38)
DLAEBA	Spatterdock	(39)

GLYPHOSATE, ISOPROPYLAMINE SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Applications may be made using any type of equipment outlined under Methods of Application, except as indicated in use paragraphs.

/23001AA /24001AA /24003AA /24006AA /24007AA	Alfalfa Barley Oats Sorghum (Milo) Wheat	0.2 ppm (fresh alfalfa and alfalfa hay) 0.1 ppm (grain crops) Do not graze or feed treated foliage to livestock within 8 weeks after application. The combined total of all treatments must not exceed 6 lb a.e./A per year. Do not plant subsequent crops other than those registered for glyphosate for 1 year following application.
	0.75-1.5 (3 lb/gal SC/L)	Preplant. Broadcast. Annual weed control. Use the higher dosage when weeds are more than 6 inches tall.
	0.75-3.75 (3 lb/gal SC/L)	Preplant. Broadcast. Perennial weed control.
	3-6 lb a.e./100 gal (3 lb/gal SC/L)	Postemergence. Spot treatment. Apply prior to heading of small grains and milo. Do not treat more than 10 percent of the total field area to be harvested.
/03001AA /03005AA /03007AA /03008AA /03011AA /03009AA	Almond Filbert Macadamia Nut Pecan Pistachio Walnut	0.2 ppm (nuts) 1.0 ppm (almond hulls) Twenty-one day preharvest interval. Do not graze or feed treated foliage to livestock within 8 weeks after application. Refer to Apple cluster for general information and use and dose instructions.

GLYPHOSATE, ISOPROPYLAMINE SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
/05001AA /05003AA /05005AA /05006AA	Apricot Nectarine Plum Prune	0.2 ppm (stone fruits) Fourteen day preharvest interval. Do not graze or feed treated forage to livestock within 8 weeks after application. General Information: Any appropriate method of application may be used in AZ, CA, CO, ID, ND, OK, OR, TX, UT and WA. In all other states use wiper equipment only. Refer to Apple cluster for general information and use and dose instructions.
/14009AA /28001AA /13001AA /14001AA /13007AA /14003AA /13008AA /13003AA /14008AA /13011AA /15011AA /13011AA /13021AA /15015AA /14011AA /28016AA /14013AA /14014AA /13024AA /25002AA /14018AA	Artichoke (Jerusalem) Beans Beet Greens Beets (red) Cabbage Carrot Cauliflower Chicory Horseradish Kale Lentils Lettuce Mustard Greens Okra Onion Peas Potato (Irish) Radish Spinach Sugar Beets Sweet Potato	0.2 ppm (leafy vegetables, root crop vegetables, seed and pod vegetables, seed and pod vegetable forage and hay) Do not graze or feed treated foliage to livestock within 8 weeks after application. The combined total of all treatments must not exceed 6 lb a.e./A per year. Do not plant subsequent crops other than those registered for glyphosate for 1 year following application.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Annual weed control. Use the higher dosage where weeds are more than 6 inches tall.
	0.75-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Perennial weed and brush control.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
06002AA	Banana	0.2 ppm Do not graze or feed treated foliage to livestock within 8 weeks after application. General Information: Delay application for 3 months after transplanting to allow plants to become established. Refer to Apple cluster for general information and use and dose instructions.
	Barley	See Alfalfa cluster.
33017BA	Bermudagrass (seed crop)	N.F. (seed) 0.2 ppm (forage grasses)
	0.28 (3 lb/gal SC/L)	Dormant application. Broadcast. For the control of annual bluegrass. Apply to actively growing annual bluegrass prior to initiation of bermudagrass greenup in the spring. Apply in 5 to 20 gallons of water per acre with a nonionic surfactant.
	Cabbage	See Artichoke (Jerusalem) cluster.
	Carrot	See Artichoke (Jerusalem) cluster.
	Cauliflower	See Artichoke (Jerusalem) cluster.
	Cherry	See Apple cluster.
	Chicory	See Artichoke (Jerusalem) cluster.
07002AA	Coffee	1 ppm (coffee beans) Fourteen day preharvest interval. Do not graze or feed treated foliage to livestock within 8 weeks after application. General Information: Delay application for 3 months after transplanting to allow plants to become established. Refer to Apple cluster for general information and use and dose instructions.

GLYPHOSATE, ISOPROPYLAMINE SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	Corn (continued)	
	1.5-3 (3 lb/gal SC/L)	At planting or preemergence in minimum tillage systems. Perennial weed control. At normal application dates in minimum tillage systems, weeds may not be at proper growth stage for control. When applied under these conditions, application will provide top kill and will reduce competition from many emerged perennial grasses and broadleaf weeds. To spray at the desired growth stage, it may be necessary to apply glyphosate alone in the late summer or fall and then follow with a label approved seedling weed control program at planting. Tank mix with alachlor; alachlor plus atrazine; alachlor plus bladex; alachlor plus simazine; or atrazine plus simazine.
	3-6 lb a.e./100 gal (3 lb/gal SC/L)	Postemergence. Spot Treatment. Apply prior to silking of corn. Do not treat more than 10 percent of the total field area to be harvested.
007AA	Cotton	15 ppm (cottonseed, forage, hay) Seven day preharvest interval. Do not graze treated fields or feed treated forage to livestock. The combined total of all applications must not exceed 6 lb a.e./A per year. Do not plant subsequent crops other than those registered for glyphosate for 1 year following application. General Information: Do not apply to crops grown for seed.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Annual weed control. Use the higher dosage for weeds over 6 inches tall.
	0.75-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Perennial weed and brush control.
	3-6 lb a.e./100 gal (3 lb/gal SC/L)	Postemergence. Spot treatment. Apply prior to boll opening. Do not treat more than 10 percent of the total field area to be harvested.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
014AA	Grapes	0.2 ppm Fourteen day preharvest interval. The combined total of all applications must not exceed 7.95 lb a.e./A per year. General Information: Avoid contact of spray with green foliage, green bark, suckers, or vines and renewals less than 3 years of age. In the northeast and Great Lakes regions, apply prior to the end of bloom stage of grapes. Refer to Apple cluster for general information and use and dose instructions.
066BA	Grasses Grown for Seed	N.F. (seed) 0.2 ppm (forage grasses) Do not feed or graze treated areas within 8 weeks after application. General Information: Do not disturb soil before treatment. Tillage should be delayed for 7 days after application. Delay planting to determine if there is any regrowth from underground parts. Where repeat applications are necessary, allow sufficient regrowth of vegetation. Summer or fall applications provide best control of warm season grasses.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Site preparation. Broadcast. Annual weed control. Use the higher dosage when weeds are over 6 inches tall.
	1.5-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Site preparation. Perennial weed and woody brush control. Repeat treatment may be necessary to control plants generating from underground rhizomes or late germinating weeds.
006AA 010AA	Guava Papaya	0.2 ppm One day preharvest interval. Do not graze or feed treated foliage to livestock within 8 weeks after application. Refer to Apple cluster for general information and use and dose instructions.
	Horseradish	See Artichoke (Jerusalem) cluster.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
30004AA	Peach	0.2 ppm Fourteen day preharvest interval. Do not graze on feed treated foliage to livestock within 8 weeks after application.
	0.75-3.75 or 3 lb a.e./4 gal (3 lb/gal SC/L)	Use limited to AL, AR, FL, NC, SC and TN. Directed spray. Apply with a shielded boom sprayer or shielded wiper applicator. When using a shielded wiper applicator, dilute 1 gallon of product in 4 gallons of water. To avoid injury, apply no later than 90 days after first bloom. Remove suckers and low hanging limbs at least 10 days prior to application. Avoid making applications near trees with recent pruning wounds. Apply near trees that are 2 or more years old.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Use limited to AZ, CA, CO, ID, ND, OK, OR, TX, UT and WA. Broadcast. Annual weed control. Use the higher dosage when weeds are over 6 inches tall.
	0.75-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Use limited to AZ, CA, CO, ID, ND, OK, OR, TX, UT, and WA. Broadcast. Perennial weed and brush control.
	3 lb a.e./4 gal (3 lb/gal SC/L)	Use limited to states other than AZ, CA, CO, ID, ND, OK, OR, TX, UT and WA. Wiper applications.
	Peas	See Artichoke (Jerusalem) cluster.
28015AA	Peanuts	0.1 ppm (peanuts) 0.5 ppm (forage, hay, hulls) The combined total of all treatments must not exceed 6 lb a.e./A per year. Do not plant subsequent crops other than those registered for glyphosate for 1 year following application.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Annual weed control. Use the higher dosage when weeds are more than 6 inches tall.
	0.75-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Perennial weed and brush control.

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
Soybeans (continued)	
1.5-3 (3 lb/gal SC/L)	At planting or preemergence in minimum tillage systems. Perennial weed control. At normal application dates in minimum tillage systems, weeds may not be at proper growth stage for control. When applied under these conditions, application will provide top kill and will reduce competition from many emerged perennial grass and broadleaf weeds. To spray at the desired growth stage of weeds, it may be necessary to apply glyphosate alone in the late summer or fall and then follow with a label approved seedling weed control program at planting. Tank mix with alachlor; alachlor plus atrazine; alachlor plus bladex; alachlor plus simazine; or atrazine plus simazine.
3-6 lb a.e./100 gal (3 lb/gal SC/L)	Postemergence. Spot treatment. Apply prior to initial pod set. Do not treat more than 10 percent of the total field area to be harvested.
Spinach	See Artichoke (Jerusalem) cluster.
Sugar Beets	See Artichoke (Jerusalem) cluster.
5003AA Sugarcane	2.0 ppm (sugarcane) 30 ppm (sugarcane molasses) Do not graze or feed treated foliage to livestock within 8 weeks after application. The combined total of all treatments must not exceed 7.95 lb a.e./A per year. General Information: Do not apply to vegetation in or around ditches, canals or ponds containing water to be used for irrigation.
0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Annual weed control. Use the higher dosage when weeds are over 6 inches tall.
0.75-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Preplant. Broadcast. Perennial weed control.

GLYPHOSATE, ISOPROPYLAMINE SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
	(Non-Crop and General Outdoor Treatments)	
0020A	Fallowland	N.F. Do not plant field crops other than those registered for glyphosate for 1 year following application. The combined total of all treatments must not exceed 6 lb. a.e./A per year. General Information: These dosages may also be used in reduced tillage systems prior to emergence of the crop. Do not apply dicamba, dimethylamine salt or 2,4-D, dimethylamine salt tank mixtures by air in CA. Some crop injury may occur if dicamba, dimethylamine salt is applied within 45 days of planting. Refer to specific product labels for crop rotation restrictions of tank mix chemicals.
	0.19 (3 lb/gal SC/L)	Preplant. Broadcast. For the control of foxtail. Apply by ground in 3 to 10 gallons or by air in 3 to 5 gallons of water per acre with a nonionic surfactant.
	0.28 (3 lb/gal SC/L)	Preplant. Broadcast. For the control of downy brome, volunteer barley, barnyardgrass, jagged chickweed, mustard (blue, tansy, tumble, wild), volunteer rye and volunteer wheat. Apply by ground in 3 to 10 gallons or by air in 3 to 5 gallons of water per acre with a nonionic surfactant.
	0.38 (3 lb/gal SC/L)	Preplant. Broadcast. For the control of annual ryegrass, bulbous bluegrass, lambsquarters, field pennycress, smallseed falseflax and wild oats. Apply by ground in 3 to 10 gallons or by air in 3 to 5 gallons of water per acre with a nonionic surfactant.
	0.28 (3 lb/gal SC/L)	Preplant. Broadcast. For the control of field bindweed, kochia, lambsquarters, prickly lettuce, redroot pigweed and Russian thistle. Tank mix with dicamba, dimethylamine salt.
	0.38 (3 lb/gal SC/L)	Preplant. Broadcast. For the control of kochia, prickly lettuce and Russian thistle. Tank mix with 2,4-D, dimethylamine salt.

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
0017AA	Bermudagrass (Common and Coastal)	
	0.75-1.13 (3 lb/gal SC/L)	Roadside release of bermudagrass. For partial control of rhizome johnsongrass. Some injury may result from application, but regrowth will occur under moist conditions. Repeat applications during the same season are not recommended.
	0.75 (3 lb/gal SC/L)	Roadside release of bermudagrass. For control of johnsongrass. Some injury may occur, but regrowth will occur under moist conditions. Tank mix with sulfometuron methyl.
0000A	Ornamentals	
		General Information: Any ornamental species may be planted following preplant applications. When repeat applications are necessary, do not exceed 7.95 pounds a.e./A per year.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Site preparation. Annual weed control. Use the higher dosage when weeds are over 6 inches tall. Repeat treatments may be necessary to control late germinating weeds.
	1.5-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Site preparation. Perennial weed and woody brush control.
0008AA	Ornamental Turf	
		General Information: Do not disturb soil before treatment. Renovation techniques should be delayed for 7 days after application. Turfgrass may be planted after control is evident. Where existing vegetation is growing under mowed conditions, apply after omitting at least 1 mowing to allow sufficient vegetative growth. Where repeat applications are necessary, allow sufficient regrowth of vegetation. Summer or fall applications provide best control in warm season grasses.
	0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Turf renovation or site preparation. Broadcast. Annual weed control. Use the higher dosage when weeds are over 6 inches tall.

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations

Airports cluster (continued)

0.75-1.5 or 3 lb a.e./100 gal (3 lb/gal SC/L)	Annual weed control in industrial, recreational and public areas. Use the higher dosage when weeds are over 6 inches tall. May be tank mixed with bromacil and diuron; simazine; or oryzalin.
1.5-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Perennial weed and woody brush control in industrial, recreational and public areas. May be tank mixed with bromacil and diuron; simazine; or oryzalin.
1.5-2.25 (3 lb/gal SC/L)	Johnsongrass control. Apply anytime from early postemergence through the boot to head stage. Tank mix with sulfometuron methyl.
	Also refer to AQUATIC NON-FOOD, Agricultural Drainage Systems cluster for additional information pertinent to Ditch Banks, Dry Ditches and Canals.

GREENHOUSE NON-FOOD CROP

(Ornamental Plants and Forest Trees)

10060A Greenhouse

3-6 lb a.e./100 gal (3 lb/gal SC/L)	Spot treatment. Thoroughly spray weed foliage. Desirable vegetation must not be present during application and air circulation fans must be turned off.

DOMESTIC OUTDOOR

(Household)

GENERAL WARNINGS AND LIMITATIONS: Make spot treatments to kill undesirable weeds and grasses around trees, shrubs, in ornamental plantings, landscaped sites or mulched areas, along sidewalks, driveways, gravelled pathways, fences, patios, around buildings, lawns, gardens, and parking areas. Overall spray applications may be made where total vegetation kill is desired for lawn renovation or landscaping. Wiper, wick or sponge type applicators may be used with undiluted concentrates where specified. If foliage of desirable plants is accidentally sprayed, immediately wash off with water. Do not cut treated vegetation for 7 days after application. Hard-to-kill weeds and grasses may require retreatment after 14 to 21 days.

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
Flower Beds cluster (continued)	
—	
(0.96% RTU)	
0100A Ornamental Lawns	General Information: Treated lawn can be reseeded or sodded after 7 days.
8 fl.oz product/gal (0.42 lb/gal SC/L) (5% SC/L)	Spot treatment.
6 fl.oz product/gal (6.6% SC/L)	
— (0.5% RTU) (0.96% RTU) (0.75% PrL)	
0.53 lb a.e./ 5,000 sq.ft or 1.25 gal product/ 5,000 sq.ft (0.42 lb/gal SC/L) (5% SC/L)	Broadcast application for lawn renovation.
0.94 gal product/ 5,000 sq.ft (6.6% SC/L)	
— (0.5% RTU)	

GLYPHOSATE, ISOPROPYLAMINE SALT

	Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
22MA	Agricultural Drainage Systems	0.1 ppm (potable water) Tolerances are established for the combined residues of glyphosate (N-phosphonomethylglycine) and its metabolite aminomethylphosphonic acid, resulting from the use of irrigation water containing residues of 0.5 ppm following applications on or around aquatic sites, at 0.1 ppm on the crop groupings citrus, cucurbits, forage grasses, forage legumes, fruiting vegetables, grain crops, leafy vegetables, nuts, pome fruits, root crop vegetables, seed and pod vegetables, stone fruit, and individual commodities cottonseed, hops, and avocados. Where no tolerances are established at higher levels from other uses of glyphosate in or on the subject crops, the higher tolerance should also apply to residues from the aquatic uses cited in this paragraph.
13MB	Ditch Banks, Dry Ditches and Canals	
21MA	Irrigation Systems	
31MA	Lakes, Ponds, and Seeps	
15MA	Reservoirs	
32MA	Rivers and Streams	
13MA	Drainage Systems	
	0.75-1.5 (3 lb/gal SC/L)	Annual weed control. Use the higher dosage for weeds that are over 6 inches tall. Apply with boom, high-volume or hand-held equipment. Thoroughly spray weed foliage. Spray gallonage should be increased with an increase in density of weeds.
	1.5-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Perennial weed, woody brush and aquatic weed control. Use the higher dosage for control of aquatic weeds. Apply with boom, high-volume or hand-held equipment. Repeat treatments may be necessary.
		Refer to TERRESTRIAL NON-FOOD CROP, Airports cluster for additional information pertinent to Ditch Banks, Dry Ditches and Canals.

Site, Dosage and Formulation (lb a.e./A)	Tolerance, Use, Limitations
Christmas Tree Plantations (continued)	
1.5-3.75 or 3-6 lb a.e./100 gal (3 lb/gal SC/L)	Directed spray. Perennial weed and woody brush control in established silvicultural sites. Application may be made by any suitable ground equipment. Thoroughly spray weed foliage, but avoid spray contact with foliage or green bark of desirable plants. Repeat treatments may be necessary to control plants regenerating from underground rhizomes or late germinating seeds.
39AA Douglas-Fir (forest) 43AA Fir (forest) 46AA Hemlock (forest) 59AA Pine (forest) 64AA Spruce (forest) 49AA Western Hemlock (forest)	General Information: Do not use over-the-top broadcast applications in silvicultural nurseries or Christmas tree plantations. Apply only where conifers have been established for more than a year. Some injury to treated conifers will result where spray patterns overlap, or the higher dosages are used, or when applications are made during periods of active conifer growth. Application may be made by air, or by any suitable ground equipment.
1.13-1.5 (3 lb/gal SC/L)	Use limited to areas East of the crest of the Cascades, except AL, AK, GA, LA, MS, NC, SC, TN, TX and VA. Conifer release. Broadcast. Apply after dormancy in fall or prior to bud swell in the spring. In fall, apply before major leaf fall of the undesirable deciduous species, although some autumn colors may be present.
0.75 (3 lb/gal SC/L)	Use limited to areas West of the crest of the Cascades. Conifer release. Broadcast. Spring application. Apply prior to bud swell for control of annual weeds.
0.75-1.13 (3 lb/gal SC/L)	Use limited to areas West of the crest of the Cascades. Conifer release. Broadcast. Fall application. Apply before leaf abscission of undesirable deciduous species, although some autumn colors may be present. Use only the lower dosage on western hemlock.

GLYPHOSATE, ISOPROPYLAMINE SALT

Listing of Registered Pesticide Products by Formulation

3.0002 3 lb/gal formulation intermediate
glyphosate, isopropylamine salt (103601)
000524-00339

4.0002 4 lb/gal formulation intermediate
glyphosate, isopropylamine salt (103601)
000524-00318

2.0002 62% formulation intermediate
glyphosate, isopropylamine salt (103601)
000524-00333

1.0412 1.04 lb/gal emulsifiable concentrate
glyphosate, isopropylamine salt (103601) plus alachlor (090501)
000524-00341

0.4215 0.42 lb/gal soluble concentrate/liquid
glyphosate, isopropylamine salt (103601)
000239-02469 000769-00497 046515-00003

3.0015 3 lb/gal soluble concentrate/liquid
glyphosate, isopropylamine salt (103601)
000524-00308 000524-00326

4.0015 4 lb/gal soluble concentrate/liquid
glyphosate, isopropylamine salt (103601)
000524-00343

5.0015 5% soluble concentrate/liquid
glyphosate, isopropylamine salt (103601)
007401-00306 034911-00025

6.6015 6.6% soluble concentrate/liquid
glyphosate, isopropylamine salt (103601)
000802-00534

0.5016 0.5% liquid-ready to use
glyphosate, isopropylamine salt (103601)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

0.9616 0.96% liquid-ready to use
glyphosate, isopropylamine salt (103601)
000524-00330 000769-00537

1.0016 1% liquid-ready to use
glyphosate, isopropylamine salt (103601)
007401-00357

Appendix A

Listing of Common Chemical Names Used on the Entry

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
030029	2,4-D, dimethylamine salt	2,4-dichlorophenoxyacetic acid, dimethylamine salt
100101	Bladex	2-[[4-chloro-6-(ethylamino)-s-triazin-z-yl]amino]-2-methylpropionitrile
101101	Metribuzin	4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one
122001	Sulfometuron methyl	methyl 2-[[[[(4,6-dimethyl-2-pyrimidinyl)amino]-carbonyl]amino]-sulfonyl]benzoate

Listing of Registration Numbers By Site and Formulation (continued)

3001AA Barley
(3 lb/gal SC/L)
000524-00308 000524-00326

3001AA Beans
(3 lb/gal SC/L)
000524-00308 000524-00326

(0.96% RTU)
000524-00330

3001AA Beet Greens
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

4001AA Beets (red)
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

3017BA Bermudagrass (seed crop)
(3 lb/gal SC/L)
000524-00308

3007AA Cabbage
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

4003AA Carrot
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

Listing of Registration Numbers By Site and Formulation (continued)

42AA Gardens
(5% SC/L)
007401-000306 034911-00025

(0.5% RTU)
007401-00304

(1% RTU)
007401-00357

02AA Grapefruit
(3 lb/gal SC/L)
000524-00308 000524-00326

(0.96% RTU)
000524-00330

14AA Grapes
(3 lb/gal SC/L)
000524-00308 000524-00326

(0.96% RTU)
000524-00330

066BA Grasses Grown for Seed
(3 lb/gal SC/L)
000524-00308 000524-00326

006AA Guava
(3 lb/gal SC/L)
000524-00308

008AA Horseradish
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

AA Kale
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

Listing of Registration Numbers By Site and Formulation (continued)

)21AA Mustard Greens
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

)03AA Nectarine
(3 lb/gal SC/L)
000524-00308

)03AA Oats
(3 lb/gal SC/L)
000524-00308 000524-00326

)15AA Okra
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

)11AA Onion
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

)06AA Orange
(3 lb/gal SC/L)
000524-00308 000524-00326

(0.96% RTU)
000524-00330

010AA Papaya
(3 lb/gal SC/L)
000524-00308

035AA Pastures
(3 lb/gal SC/L)
000524-00308

004AA Peach
(3 lb/gal SC/L)
000524-00308

Listing of Registration Numbers By Site and Formulation (continued)

014AA Radish
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

006AA Sorghum (Milo)
(3 lb/gal SC/L)
000524-00308 000524-00326

023AA Soybeans
(3 lb/gal SC/L)
000524-00308 000524-00326

(1.04 lb/gal EC)
000524-00341

024AA Spinach
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

002AA Sugar Beets
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

003AA Sugarcane
(3 lb/gal SC/L)
000524-00308 000524-00326

018AA Sweet Potato
(3 lb/gal SC/L)
000524-00308

(0.96% RTU)
000524-00330

007AA Tangelo
(3 lb/gal SC/L)
000524-00308 000524-00326

(0.96% RTU)
000524-00330

Listing of Registration Numbers By Site and Formulation (continued)

3017AA Bermudagrass (Common and Coastal)
(3 lb/gal SC/L)
000524-00308

031AA Boxwood
(3 lb/gal SC/L)
000524-00308 000524-00326

013AA Euonymus
(3 lb/gal SC/L)
000524-00308 000524-00326

051AA Fir
(3 lb/gal SC/L)
000524-00308 000524-00326

056AA Flowering Crabapple
(3 lb/gal SC/L)
000524-00308 000524-00326

070AA Holly
(3 lb/gal SC/L)
000524-00308 000524-00326

088AA Ligustrum
(3 lb/gal SC/L)
000524-00308 000524-00326

089AA Lilac
(3 lb/gal SC/L)
000524-00308 000524-00326

082AA Magnolia
(3 lb/gal SC/L)
000524-00308 000524-00326

083AA Maple
(3 lb/gal SC/L)
000524-00308 000524-00326

093AA Oak
(3 lb/gal SC/L)
000524-00308 000524-00326

00000A Ornamentals
(3 lb/gal SC/L)
000524-00308 000524-00326

Listing of Registration Numbers By Site and Formulation (continued)

)090A Industrial Plant Sites, Lumberyards, Petroleum Tank Farms and Pumping Installations, Storage Areas
(3 lb/gal SC/L)
000524-00308 000524-00326

)110A Parking Areas
(3 lb/gal SC/L)
000524-00308 000524-00326

)060A Pipeline, Power and Telephone Rights-of-Way
(3 lb/gal SC/L)
000524-00308 000524-00326

0050A Railroads
(3 lb/gal SC/L)
000524-00308 000524-00326

0000A Uncultivated Agricultural Areas, Farmstead Building Foundations
(3 lb/gal SC/L)
000524-00308 000524-00326

GREENHOUSE NON-FOOD CROP

(Ornamental Plants and Forest Trees)

0060A Greenhouse
(3 lb/gal SC/L)
000524-00308

Listing of Registration Numbers By Site and Formulation (continued)

0110A Driveways, Parking Areas, Sidewalks

(5% SC/L)
007401-00306 034911-00025 046515-00003

(6.6% SC/L)
000802-00534

(0.42 lb/gal SC/L)
000239-02469 000769-00497

(0.5% RTU)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

(0.96% RTU)
000524-00330 000769-00537

(1% RTU)
007401-00357

(0.75% PrL)
000239-02466

70150A Fencerows

(5% SC/L)
007401-00306 034911-00025 046515-00003

(6.6% SC/L)
000802-00534

(0.42 lb/gal SC/L)
000239-02469 000769-00497

(0.5% RTU)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

(0.96% RTU)
000524-00330 000769-00537

(1% RTU)
007401-00357

(0.75% PrL)
000239-02466

Listing of Registration Numbers By Site and Formulation (continued)

1000A Ornamental Lawns

(5% SC/L)
007401-00306 034911-00025 046515-00003

(6.6% SC/L)
000802-00534

(0.42 lb/gal SC/L)
000239-02469 000769-00497

(0.5% RTU)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

(0.96% RTU)
000524-00330 000769-00537

(0.75% PrL)
000239-02466

1010A Ornamental Trees and Shrubs

(5% SC/L)
007401-00306 034911-00025 046515-00003

(6.6% SC/L)
000802-00534

(0.42 lb/gal SC/L)
000239-02469 000769-00497

(0.5% RTU)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

(0.96% RTU)
000524-00330 000769-00537

(1% RTU)
007401-00357

(0.75% PrL)
000239-02466

Listing of Registration Numbers By Site and Formulation (continued)

)000A Storage Areas, Vacant Lots, Yards

(5% SC/L)
007401-00306 034911-00025 046515-00003

(6.6% SC/L)
000802-00534

(0.42 lb/gal SC/L)
000239-02469 000769-00497

(0.5% RTU)
000239-02467 000769-00523 000802-00535 007401-00304
007401-00307 046515-00002

(0.96% RTU)
000524-00330 000769-00537

(1% RTU)
007401-00357

(0.75% PrL)
000239-02466

AQUATIC FOOD CROP

(Agricultural Crop)

004AA Rice

(3 lb/gal SC/L)
000524-00308

AQUATIC NON-FOOD

(Aquatic Sites)

022MA Agricultural Drainage Systems

(4 lb/gal SC/L)
000524-00343

GLYPHOSATE, ISOPROPYLAMINE SALT

Appendix B

Listing of Registration Numbers By Site and Formulation (continued)

00AA Forest Trees
(3 lb/gal SC/L)
000524-00308 000524-00326

046AA Hemlock (forest)
(3 lb/gal SC/L)
000524-00308 000524-00326

097AA Loblolly Pine (forest)
(3 lb/gal SC/L)
000524-00308

059AA Pine (forest)
(3 lb/gal SC/L)
000524-00308 000524-00326

006AA Silvicultural Nurseries
(3 lb/gal SC/L)
000524-00308 000524-00326

104AA Slash Pine (forest)
(3 lb/gal SC/L)
000524-00308

064AA Spruce (forest)
(3 lb/gal SC/L)
000524-00308 000524-00326

149AA Western Hemlock (forest)
(3 lb/gal SC/L)
000524-00308 000524-00326

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Number). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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GS0178-020	Storherr, R. (1981) Letter sent to M. Nelson dated Jan 19, 1981: Method trial on PP #0F2329, glyphosate in or on peanuts, by an HPLC procedure. 3 p.
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IV. FORMS APPENDICIES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data
EPA Form 8580-	Product Specific Data Report (End-Use Products)
EPA Form 8580-	Formulator's Exemption Statement

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE	
ACTIVE INGREDIENT	

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. _____ Product Name _____

Applicant's Name and Address _____

_____

_____

_____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): _____

_____

_____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated _____ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature _____

Date _____ Title _____

EPA Form (April 1985)